Achieving Best Practices in the Use of Hysterectomy

Report of Ontario's Expert Panel on Best Practices in the Use of Hysterectomy

Ontario Women's Health Council

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Achieving Best Practices in the Use of Hysterectomy

February 2002

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The Ontario Women's Health Council is fully funded by the Ontario Ministry of Health and Long-Term Care. This report does not necessarily reflect endorsement by the Ministry of Health and Long-Term Care.

N. Jane Pepino, C.M., Q.C.
Chair, Ontario Women's Health Council
2nd Floor, 880 Bay Street
Toronto, Ontario
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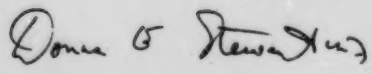
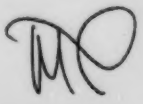
Dear Ms. Pepino:

The Expert Panel on Best Practices in the Use of Hysterectomy was assembled at the request of the Ontario Women's Health Council to develop evidence-based recommendations for best practices in the management of the discretionary indications for hysterectomies. Our multidisciplinary team has now concluded its deliberations and hereby respectfully submits its findings and recommendations.

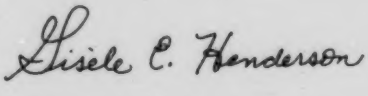
Yours very truly,



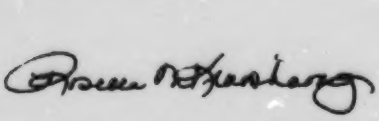
Donna E. Stewart, Chair



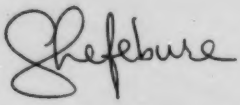
Michael Evans



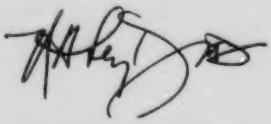
Gisèle Henderson



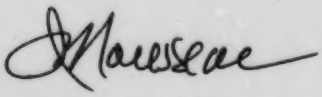
Rosella M. Kinoshameg



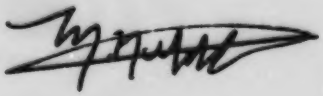
Guylaine Lefebvre



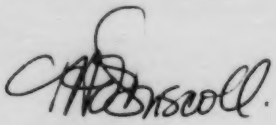
Nicholas A. Leyland



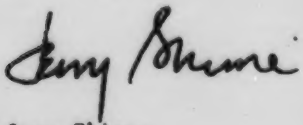
Johanne Mousseau



Melissa Nutik



Terry O'Driscoll



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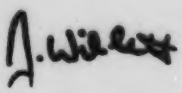

Janice Willett

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Executive Summary

Hysterectomy is one of the most common surgical procedures performed on women. The 1998/99 National Population Health Survey noted that 22% of women in Canada aged 35 or older (1.8 million women) have had a hysterectomy. The majority of procedures are carried out for discretionary reasons, meaning those indications other than cancer or pre-cancerous states, and as such are often performed to enhance the quality of a woman's life rather than to save her life.

Canada has experienced a significant decrease in the rate of hysterectomy since 1981. Although the numbers are notably less than in the United States, Canada still performs hysterectomies at double the rates of Britain, Sweden, the Netherlands and Norway. There is concern among the medical and health policy community as well as among women that hysterectomy is used too frequently as a first line of treatment.

Ontario's rate of hysterectomy has experienced a comparable decline since 1981. However, variation in hysterectomy rates between counties remains large with more than twice the rates in the North and Southwest regions of the Province compared to Toronto and Peel. Greatest discrepancy is seen in rural and/or northern regions compared to urban centres with teaching hospitals. Other notable factors which appear to influence the variation are pre-surgical diagnosis and socio-economic indicators, especially education.

In order to address the issues surrounding the variation in hysterectomy rates, the Ontario Women's Health Council convened an Expert Panel to develop evidence based recommendations for best practices in the management of the discretionary indications for hysterectomy. As part of the Expert Panel's work,

- Members presented research and experience from specialty areas, and conducted exhaustive literature searches.
- Health care professionals and women investigated and reviewed availability of patient education materials.
- Women in Northern Ontario participated in discussion groups to answer such questions as:
  - Where do you get information about benign uterine conditions and hysterectomy?
  - What influences your choice of treatment?
  - What alternative therapies are presented?

Summary of Findings

Challenges to the use of best practices related to benign uterine conditions and hysterectomy include:

- Less than optimal availability of patient education information;
- Shortages of health care practitioners; and
- Lack of access to current medical and surgical therapies.

These challenges are particularly significant in Northern and rural/remote Ontario.

RECOMMENDATIONS

In order to improve care related to benign uterine conditions for the women of Ontario and promote the appropriate use of hysterectomy, the following recommendations are presented:

PATIENT EDUCATION, SATISFACTION AND QUALITY OF LIFE

1. Develop and disseminate a range of accurate information and decisional support tools for women about conditions and treatment options related to benign uterine conditions that are linguistically and culturally appropriate.

   Topics must include:

   i. Normal and abnormal menstrual periods, abnormal inter-menstrual bleeding, fibroids, chronic pelvic pain, endometriosis, uterine prolapse, urinary incontinence, menopause, and measurement tools for uterine bleeding.

   ii. Investigational procedures such as hysteroscopy, laparoscopy, vaginal ultrasound, endometrial biopsy, and dilatation and curettage.

   iii. Treatment options such as medical treatments, ablation therapies, hysteroscopy, embolization, myomectomy and various types of hysterectomy.

   iv. Indications, limitations, and possible complications and outcomes of all treatments.

   Information formats must:

   i. Include pamphlets, media coverage, decision-making kits, videotapes, audiotapes, internet, Telehealth, support groups, and workshops and symposia.

   ii. Be available from multiple sources including family doctors, gynaecologists, nurse practitioners, public health nurses, health centres, pharmacies and community health centres.

   iii. Be written at grade 6 literacy level and available in English, French and other major languages of the health district.

2. Correct through education the misperception in some areas that hysterectomy is a normal and desirable event after childbearing is completed.

3. Consider the challenges to Northern and rural/remote Ontario women which include a shortage of family doctors, gynaecologists and nurse practitioners as well as the barriers imposed by geography (distance, roads, weather), literacy, economics and lack of alternative medical equipment.

   i. Develop regional women's health centres in the north and provide care and equipment to treat high priority women's health problems including gynaecological conditions.

   ii. Include education and decisional supports for benign uterine conditions in the Ontario Mandatory Health Programs and Service Guidelines by linking the reproductive health, sexual health and chronic disease prevention programs and ensuring adequate funding for implementation.

   iii. Enhance the visiting specialist program for gynaecologists in the North and adequately reimburse the program in order to attract participants.

   iv. Continue travel grants for patients to visit specialists.

4. Provide resources to address psychosocial issues related to benign uterine conditions (e.g. depression, anxiety, relationship issues, fertility, sexuality, and abuse) through education, professional evaluation, counseling and support groups before, during and following treatment.

5. Ensure through drug subsidies that all women have equal access to hormonal treatments for abnormal uterine bleeding.

EDUCATION AND AVAILABILITY OF HEALTH CARE PROVIDERS

TRAINEES

6. The Council of Ontario University Programs in Nursing (COUPN) and the Council of Ontario Faculties Medicine (COFM), in consultation with other appropriate organizations, develop an information and education plan for undergraduates and postgraduates to promote mutual understanding of roles between health care professions.

7. Ontario's medical schools, in collaboration with the Ontario and federal governments, continue to take steps to develop rural medical education at the undergraduate and post graduate level.
8. Ontario's education programmes for nurse practitioners, in collaboration with the Ontario and federal governments, continue to provide educational opportunities to prepare Registered Nurses in the Extended Class (RN(EC)s) to work in rural communities.
9. Emphasize the diagnosis and management of abnormal uterine bleeding in the core curriculum for nurse practitioners and family practitioners including:
   i. Endometrial biopsy.
   ii. Medical management of abnormal uterine bleeding.
10. Emphasize training in hysteroscopy and hysteroscopic procedures for postgraduates in gynaecology.

PRACTITIONERS

11. Develop, in conjunction with the relevant professional organizations, continuing education (CE) initiatives in a range of formats for the diagnosis and management of benign uterine disorders.
12. Develop a 'toolkit' that includes products that increase knowledge (e.g. guidelines) but also enable best practice (e.g. consumer information and decision aids, awareness of local resources, algorithm, etc.). The toolkit must be bundled with an academic outreach initiative (e.g. CE, academic detailing, etc.) and preferably evaluated.
13. Assist practitioners in rural and remote areas through funding and locums to attend continuing education events.
14. Develop and support preceptor programs including clinical traineeships for individual practitioners to learn and/or upgrade:
   i. Diagnostic skills and management protocols for benign uterine conditions.
   ii. Vaginal hysterectomy and laparoscopic techniques for hysterectomy.

AVAILABILITY AND UTILIZATION OF HEALTH CARE HUMAN RESOURCES

15. Review and revise the approved list of laboratory tests for RN(EC)s to include the ordering of pathology examination of endometrial biopsies.
16. Promote the utilization of RN(EC)s in Ontario by enabling all physicians, including fee-for-service physicians, to work with RN(EC)s, through appropriate incentives and compensation.
17. Develop innovative recruitment, retention and replacement strategies for family physicians, RN(EC)s and specialists for under-serviced communities.
18. Establish appropriate compensation for medical specialists to provide referral and consultation support for RN(EC)s.
19. Address the alarming attrition rate of obstetricians and gynaecologists.
20. Provide incentives to family practitioners to repatriate them to the practice of low risk obstetrics.
21. Develop a model of comprehensive, integrated well woman care that is accessible to all women in Ontario.

MEDICAL AND SURGICAL MANAGEMENT OF BENIGN UTERINE CONDITIONS

22. Make hysteroscopic and global endometrial ablation procedures more widely available to women throughout Ontario by designating funding and situating these procedures in outpatient centers and ambulatory surgical facilities.
23. Encourage the use of the most clinically appropriate route of hysterectomy through various strategies including the development of a decision tree and preferential reimbursement, recognizing the expertise and time required to perform these surgeries.
24. Consider including saline sonohysterography in the Ontario Physician Schedule of Benefits. (Note: included as of April 1, 2002.)

RECOMMENDATIONS FOR FUTURE RESEARCH

25. Commission research to evaluate:
    i. Quality of life issues for women with benign uterine conditions.
    ii. Availability and acceptability of information and decision-making aids related to treatment for benign uterine conditions.
    iii. Patient satisfaction and outcomes with various treatment options for benign uterine conditions, including endometrial ablation as an alternative to medical management in the treatment of abnormal uterine bleeding.
    iv. Clinical trials of new and emerging technologies for endometrial ablation and the treatment of fibroids including efficacy, short and long-term risks and benefits.

BACKGROUND

The Ontario Women's Health Council (OWHC) Action Plan for 2000-2001, approved by the Minister of Health and Long-Term Care in July 2000, included the establishment of an Expert Panel to develop evidence-based recommendations for best practices in the management of the discretionary indications for hysterectomy in an effort to reduce the variation in rates of hysterectomy in Ontario. The discretionary indications for hysterectomy for the purpose of this report are abnormal uterine bleeding (AUB), uterine fibroids, uterine prolapse, endometriosis, pelvic pain and other benign (non-cancerous) disorders.

PREFACE

The Ontario Women's Health Council was established to advise the Minister of Health and Long-Term Care on matters relating to women's health and to ensure that the healthcare system is responsive to the needs of women. The Ontario Women's Health Council acts as a catalyst to create linkages with government, educators, private sector, researchers, health care organizations and other community groups in the performance of its duties.

MANDATE

This project aims to promote best practices in the use of hysterectomy, specifically by:

- Improving patient education related to the discretionary indications for hysterectomy;
- Improving the management of the discretionary indications for hysterectomy; and
- Improving access to alternate forms of treatment for the discretionary indications for hysterectomy.

PROCESS

A one-day brainstorming session on AUB was convened by the OWHC to provide advice on the creation of the terms of reference for an Expert Panel. Participants included representatives from family medicine, gynaecology, nurse practitioners, women's health experts, Ministry of Health and Long Term Care (MOHLTC), the Ontario Society of Obstetricians and Gynaecologists (OSOG), the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the Ontario College of Family Physicians (OCFP). Participants identified the major issues that should be addressed by the Expert Panel and the process by which to address these issues.

Following the discussions of the AUB brainstorming session recommendations, the Ontario Women's Health Council decided to broaden the focus of the Expert Panel to include all discretionary indications for hysterectomy.

An Expert Panel was established as the lead for the project and was assigned into smaller working groups which reviewed the following areas:

- Patient Education, Satisfaction and Quality of Life
- Education and Availability of Health Care Providers
- Medical and Surgical Management of Benign Uterine Conditions.

Members of the Expert Panel and Working Groups are listed in Appendix A.

The panel agreed to accept the levels of evidence as defined by the Canadian Task Force on the Periodic Health Examination (Woolf et al., 1990). For a description of the levels of evidence, see Appendix C.

PRINCIPLES

The Expert Panel on Best Practices in the Use of Hysterectomy adopted the following principles to guide its work:

- A patient centred approach with emphasis on sensitivity to:
  - Culture;
  - Psychosocial factors;
  - Socio-economic circumstances;
  - Geography;
  - Language and educational levels; and
  - Barriers.
- Collaborative practice among all health practitioners.
- Evidence based approach to education and practice.
- Strategies must be innovative and feasible within the context of:
  - Time;
  - People;
  - Equipment;
  - Funding; and
  - Education/skill development.

VISION

All women in Ontario, regardless of age, race, culture, language, socioeconomic status, sexual orientation and geography have equal access to the best practices in the management of the discretionary indications for hysterectomy.

GOAL

To develop evidence based recommendations and strategies for best practices in the management of the discretionary indications for hysterectomy and submit these recommendations and strategies to the Ontario Women's Health Council.

INTRODUCTION

DEFINITIONS

Hysterectomy is the removal of the uterine body and cervix (total) or removal of the uterine body only (subtotal). It may also be associated with the removal of the ovaries and fallopian tubes (bilateral salpingo-oophorectomy). Hysterectomy can be performed via the abdomen or vagina depending on the surgeon, the indication for surgery, the nature of the disease and patient characteristics (Millar, 2000).

Besides the traditional approaches of abdominal or vaginal hysterectomy, it is now possible to perform hysterectomies using a laparoscope, thereby allowing hysterectomies to be performed vaginally that otherwise could only be performed through larger abdominal incisions.

DISCRETIONARY INDICATIONS

Abnormal Uterine Bleeding (AUB) is defined as an increase in frequency of menses, duration of flow or amount of blood loss (Vilos et al., 2001).

Dysfunctional Uterine Bleeding (DUB), a subcategory of AUB, is a diagnosis of exclusion when there is no pelvic pathology or underlying medical causes (Vilos et al., 2001).

Uterine Fibroids (leiomyomas) are benign growths that develop from the cells that make up the muscle of the uterus and are the most common types of growth found in a woman's pelvis. They are diagnosed in about 20 – 25% of all women, and are extremely common in women over age 30. Most women who have fibroids are not aware of them. Fibroids may grow rapidly or slowly over a number of years. Most fibroids are asymptomatic or cause only minor symptoms and do not require treatment (American College of Obstetricians and Gynecologists, 1999b).

Endometriosis is a condition in which tissue similar to that normally lining the uterus is found outside of the uterus, usually on the ovaries, fallopian tubes and other pelvic structures. Endometriosis may not cause any symptoms but can cause pain, especially during the menstrual period or during intercourse. For some women the pain is mild, for others it can be severe. Endometriosis may also cause infertility (American College of Obstetricians and Gynecologists, 1998).

Uterine Prolapse and Pelvic Support Problems arise from weakening of the muscles and ligaments supporting the pelvic organs. They may become problematic if the vaginal walls and/or the uterus protrude from the vaginal opening. Genetic factors, obesity, chronic cough, and stretching in childbirth are predisposing factors (American College of Obstetricians and Gynecologists, 1999a).

OVERVIEW

Hysterectomy is one of the most common surgical procedures performed in the western world. The majority of these procedures are carried out for discretionary reasons, meaning those indications other than cancer or pre-cancerous conditions, and as such are often performed to enhance the quality of a woman's life rather than to save her life. However, even among discretionary (non-cancerous) reasons, hysterectomy may have a role in preventing health problems such as anemia secondary to blood loss.

There is concern among the medical and health policy community that hysterectomy is used too frequently as a first line of treatment. Information from well designed studies on the effectiveness of hysterectomy for improving quality of life is limited. As well, the impact on quality of life when hysterectomy is not available has not been addressed. Both of these issues require further attention.

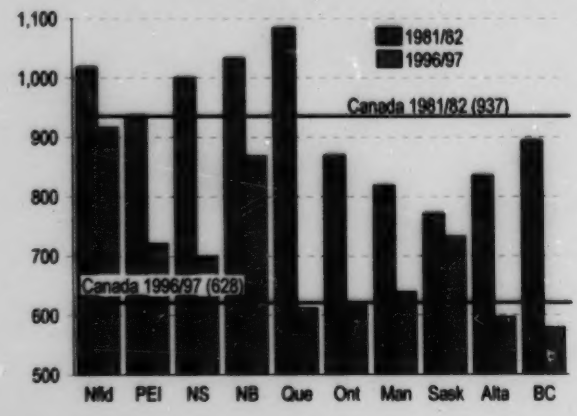
Quality of life is defined by Ferrans and Powers (1992) as "a person's sense of well-being that stems from satisfaction or dissatisfaction with areas of life that are important to him/her". The largest study in the United States to assess outcomes of hysterectomy for nonmalignant conditions (Carlson et al., 1994) was the Maine Women's Health Study, a prospective study investigating 418 women between the ages of 25 to 50 years who underwent surgery between

1989 and 1991. Significant improvement was reported for urinary symptoms, fatigue, pelvic pain, psychological symptoms and sexual functioning. An increase in the quality of life was noted and sustained for six months and one year after hysterectomy. In a second study conducted by the same research team, 380 women with a diagnosis of leiomyomas (fibroids), abnormal bleeding and/or chronic pelvic pain were managed medically and compared to 311 women with similar diagnoses but managed by hysterectomy. The major outcomes assessed were frequency and severity of physical and psychological symptoms, emotional functioning, general health and physical activity. In the group treated medically for fibroids, there were no statistically significant changes reported in symptoms or quality of life. Medical treatment for chronic pelvic pain and AUB resulted in significant improvements in symptoms, emotional functioning, general health and activity, but 23% eventually underwent hysterectomy. Of the remaining group, 25% of women with abnormal bleeding and 50% with chronic pelvic pain reported significant symptoms after one year of medical treatment. New problems following medical therapy were also reported, including bleeding (10%), pelvic pain (9%), weight gain (8%), hot flashes (7%), and depression (7%). At one year, hysterectomy was the factor most highly associated with a positive outcome after adjusting for age, reproductive history and severity of symptoms. The conclusion to this study was, for patients with chronic pelvic pain and AUB who preferred to defer or avoid surgery, medical therapy could provide an improvement in symptoms and quality of life. Hysterectomy was an effective alternative when medical management failed (Naughton and McBee, 1997).

THE CANADIAN PICTURE

Exhibit 1

AGE-ADJUSTED HYSTERECTOMY RATES, WOMEN AGED 35 OR OLDER, CANADA AND PROVINCES, 1981/82 AND 1996/97



Data Sources: *Statistics Canada, Hospital Morbidity File, 1981/82; Canadian Institute for Health Information, 1996/97*

Note: *Refers to CCP 80.2 to 80.7. Adjusted to age distribution of women aged 35 or older in 1996.*

In Canada, the annual number of hysterectomies since 1981/82 has remained stable, never falling below 46,600 or exceeding 51,600; however, the number of women over age 20 has been rising, resulting in a fall in incidence rates from 937 to 462 hysterectomies per 100,000. The National Population Health Survey of 1998/99 revealed that over 20% of women aged 35 or older (1.8 million) have had a hysterectomy. Women under age 44 years accounted for 7% of hysterectomies, rising to 37% in 65 to 74 year olds. According to 1996/97 data, abdominal hysterectomies were the most common surgery for women aged 35 and older, and vaginal hysterectomies were fourth most common (Canadian Institute for Health Information; Statistics Canada, Hospital Morbidity File).

Similar to the national trend, hysterectomy rates have fallen across the provinces, though inter-provincial and intra-provincial variations remain significant. Similar regional variations have been reported in the United States, Great Britain and Australia and are not accounted for by age distribution.

THE ONTARIO PICTURE

Ontario's hysterectomy rates have decreased significantly from 1981/82 as have those in Quebec (the greatest rate of decline), British Columbia, Alberta and Nova Scotia. Only Newfoundland and Saskatchewan demonstrated minimal reductions. Although the overall trend in Ontario has been toward decreasing hysterectomies, the significant variation in rates across regions in the province remains a concern.

Exhibit 2

AGE-ADJUSTED HYSTERECTOMY RATES, WOMEN AGED 20 OR OLDER, ONTARIO AND HEALTH REGIONS WITH POPULATIONS GREATER THAN 100,000, 1997/98

District Health Councils (DHCs)	Rate per 100,000
ONTARIO	476
Champlain	517
Quinte-Kingston and Rideau	549
Durham-Haliburton-Kawartha and Pine Ridge	580
Toronto	327
Simcoe-York	449
Halton-Peel	388
Waterloo-Wellington-Dufferin	480
Hamilton-Wentworth	484
Niagara	639
Grand River	559
Thames Valley	515
Essex-Kent and Lambton	588
Grey-Bruce-Huron and Perth	527
Muskoka-Nipissing and Parry Sound	706
Algoma-Cochrane-Manitoulin and Sudbury	743
Northwestern Ontario	617

***Source:** Statistics Canada, 2000*

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Source: Statistics Canada, 2000

Cohen and Young (1996) examined variations in hysterectomy rates between counties in Ontario. The extent of overall variation among counties was large, with rates highest in the North and Southwest regions of the province. From 1989/90 to 1994/95, the ratio of the highest to the lowest hysterectomy rate among District Health Councils was 2.5 (Cohen & Young, 1996). More recent data indicates that this trend is still present. For example, in 1998/99 the hysterectomy rate for the Algoma-Cochrane-Manitoulin and Sudbury DHC area (732 per 100,000 women aged 20 and over) was more than double the rate for the Toronto DHC (327 per 100,000 women aged 20 and over) (Basinski, 2002).

The decreases in hysterectomy rate in Ontario described in the 1994/95 Canadian Institute for Health Information (CIHI) data did not continue across the province. For the next three years, rates reached a plateau in most regions, with a subsequent decrease observed between 1998 and 2000 (Basinski, 2002). As the restructuring of hospitals and health services within the province took place at this time, it is not clear why or by what mechanisms this decrease occurred.

Ontario regions with the highest rates of hysterectomy tend to be in rural or northern areas, while regions with the lowest rates tend to be urban areas with teaching hospitals (Canadian Institute for Health Information, 2001a). There are also significant differences in hysterectomy rates based on the pre-surgical diagnosis and socio-economic indicators, especially education. For example, the incidence of hysterectomy for the diagnosis of DUB in the lowest quintile of education is approximately 1.8 compared to the highest quintile of education rate of 0.5 (Basinski, 2002). Essentially the hysterectomy rate for the diagnosis of cancer is similar across regions; however the variation in relative rate for discretionary indications is dramatic and accounts for the differential rates across the province (Basinski, 2002).

The significant variation in rate of hysterectomy throughout Ontario raises many questions. Education, income, access to services and geography all seem to be important, as well as medical practice variability and availability of health human resources.

As part of this project, interviews were conducted with gynaecologists-in-chief in the five areas of Ontario (Hastings and Prince Edward, Waterloo, Halton, Simcoe and Algoma) in which hysterectomy rates showed the greatest decreases between 1994/95 and 1998/99. Most areas had more than one hospital which performed hysterectomies, but the gynaecologist-in-chief was either a jointly appointed chief, or knowledgeable about the sister hospitals' practices and procedures. The following topics emerged as important strategies in the reduction in hysterectomy rates:

1. Staff changes
2. Medical management
3. New diagnostic and therapeutic technologies
4. Professional continuing education
5. Patient education
6. Increased primary care management of abnormal uterine bleeding
7. Quality assurance initiatives

For more information on these interviews, see Appendix D.

THE INTERNATIONAL PICTURE

In general, Europe has substantially lower rates for the discretionary indications of hysterectomy than North America. Sweden's rate of hysterectomy (based on 1998 statistics) is approximately 200 per 100,000 women (Ottosen et al., 2000). The statistics for the Netherlands are not dissimilar with a rate of 268 per 100,000 for women over 20 years of age (Brolmann et al., 2001). British statistics show an overall decline in hysterectomy rates; 290 per 100,000 in 1994, 1995 and 1996 to 230 in 1998/99 (Yuen, 2000).

The United States experienced a slight decline in hysterectomy rates during the 1980s which leveled off during the early 1990s and decreased again in the late 1990s. The United States continues to have the highest rates of hysterectomies in western world at 550 per 100,000 women (Lepine et al., 1997).

Exhibit 3

COMPARATIVE INTERNATIONAL, CANADIAN AND ONTARIO HYSTERECTOMY RATES

Country	Rate per 100,000
Sweden	200
United Kingdom	230
Netherlands	268
Canada	484
Ontario	476
United States	550

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Assessment and Diagnosis

The Society of Obstetricians and Gynaecologists of Canada (SOGC) issued updated Clinical Practice Guidelines for Hysterectomy in January 2002. The guidelines highlight a decision-making algorithm that offers a concise review of the recommended diagnostics and medical therapy options leading up to the decision for hysterectomy. The guideline states "The surgeon or gynaecologist who is prepared to perform a hysterectomy to treat dysfunctional uterine bleeding must be fully knowledgeable about all the medical alternatives to surgical management and inform the patient of her choices of treatment" (Lefebvre et al., 2002).

The SOGC also issued Guidelines for the Management of Abnormal Uterine Bleeding in August 2001 which present current diagnostic and therapeutic recommendations specific to this discretionary indication for hysterectomy. Sampling of the endometrium is recommended to diagnose malignant and pre-malignant conditions as well as to assess hormonal influences on the endometrium. Specific guidelines are presented concerning this diagnostic test, which indicate that low risk women under age 40 may not always require an endometrial biopsy. Where biopsy is indicated, guidance is given on recommended techniques. Other diagnostic procedures such as ultrasound via the transvaginal route and saline sonohysterography may also be indicated to assess the endometrium (Royal College of Obstetricians and Gynecologists, 1999; Vilos et al., 2001).

To view these guidelines, see Appendix H.

The transvaginal ultrasound is the primary diagnostic modality for the assessment of female pelvic abnormalities. Although this technique provides excellent overall depiction of the uterus and the endometrial lining as well as the ovaries, it is limited in evaluating the uterine cavity. Saline sonohysterography can significantly improve visualization of intra-cavitary lesions, such as uterine polyps not readily seen on standard transvaginal ultrasounds, as well as differentiating endometrial from intracavitary abnormalities (Cullinan et al., 1995). This procedure is well tolerated by the patient but is not currently listed under the Ontario Schedule of Benefits (OHIP) and accordingly is not available to all women in the province. (Note: saline sonohysterography became listed as of April 1, 2002.)

MANAGEMENT

ABNORMAL UTERINE BLEEDING

The SOGC Clinical Practice Guidelines for the Management of Abnormal Uterine Bleeding (Vilos et al., 2001) describe current medical management protocols as well as the surgical alternatives to treatment in detail. Dilatation and curettage (D & C), once considered a therapeutic modality, is now generally only considered as an aid to diagnosis when the endometrial biopsy is inconclusive or when underlying pathology is suspected; it is not recommended as a treatment. Treatment options following diagnosis generally begin with the least invasive modalities (medical therapies) and may progress through minimally invasive hysteroscopic or global endometrial ablation procedures with hysterectomy as the last technique in an increasingly invasive stepwise approach.

Medical management allows fertility to be preserved; the treatment is less invasive than surgery. Medications may be used to treat heavy regular menstruation, irregular anovulatory (without ovulation) menstrual bleeding, dysmenorrhea (painful menstruation), and chronic pelvic pain. Medical therapies include the following local and systemic methods:

- Antifibrinolytics, tranexamic acid
- Nonsteroidal anti-inflammatory agents (NSAID), naproxen, mefenamic acid
- Combined oral contraceptives
- Cyclic progestogens
- Gonadotrophin releasing hormone analogues (GnRH analogues)
- Androgenic agents, danazol
- Local, the progesterone laden intra-uterine device (levonorgestrel IUD)

Endometrial ablation (destruction of the endometrium, the inner lining of the uterus) has been clinically evaluated for 20 years and has shown high levels of patient satisfaction. Current guidelines (Vilos et al., 2001; American College of Obstetricians and Gynecologists, 2000) recommend endometrial ablation as an efficient and cost-effective surgical alternative to hysterectomy for the treatment of AUB. Studies of the procedure with follow up to 6.4 years have shown satisfaction rates of 85%, but within this time 20% of women required further surgery (Martyn 2000).

Global ablation procedures were introduced in the 1990s as an easier and safer method of endometrial ablation. The procedure is performed without hysteroscopic visualization (Vilos, 2000). Although preliminary results are impressive, long-term studies on efficacy, complication rates and cost effectiveness have not been completed. Newer devices are in the clinical trial phase and consequently have not received appropriate Health Canada, Medical Device licensing (Vilos et al., 2001).

UTERINE FIBROIDS

The incidence of uterine leiomyomatas (fibroids) in women older than 35 years is at least 20% – 40%. Many patients are asymptomatic and therefore do not require treatment. However, they can adversely impact a woman's quality of life and consequently are the indication for 40% – 65% of hysterectomies (Worthington-Kirsch et al., 1998). Treatment options for leiomyomas include medical management, myomectomy and hysterectomy. Medical management includes hormonal treatments such as oral contraceptives and depoprovera. Myomectomy (surgical removal of the fibroid alone) is a surgical option available for women who want to preserve fertility or who do not want to undergo hysterectomy and for women with localized intracavitary fibroids that can be removed hysteroscopically. Hysterectomy is a definitive and permanent solution when fibroids are causing symptoms such as severe bleeding, pelvic pressure and pain.

In recent years more conservative treatments have been developed to treat fibroid-related symptoms. Uterine Artery Embolization (UAE) is an experimental, interventional radiology technique that may offer an alternative to surgical procedures such as myomectomy and hysterectomy. Preliminary reports indicate this new technique is effective in controlling symptoms in 80% – 90% of selected patients, but the studies are generally small and the quality of data available is rarely optimal. Side effects and serious complications including death have been reported. Post procedural pain is common and invariably requires patient-controlled analgesic pumps (Pelage et al., 2000) The vaginal expulsion of submucosal fibroids is a rare side effect. In some cases hysterectomy has had to be performed due to acute septic uterine necrosis (Pelage et al., 2000). Potential candidates for UAE should be referred to a research centre with expertise in this procedure that also provides patient counseling and long-term follow-up and evaluation. Further investigations through well-designed clinical research trials are required.

ENDOMETRIOSIS

Endometriosis is a common condition in which symptoms are often out of keeping with surgical findings. A definitive diagnosis can only be made with laparoscopy or laparotomy and finding tissue that histologically resembles ectopic endometrium (Society of Obstetricians and Gynaecologists of Canada, 1999). Most often this tissue is found within the pelvis but may involve other structures within the abdomen. 10% – 50% of infertile women will have endometriosis present at the time of laparoscopy and in patients with pelvic pain or dysmenorrhoea it is found in 10% – 65% of women. Endometriosis is primarily seen in reproductive aged women, although it can be found after menopause. It is more common in Asian than Caucasian women and is least common in African women.

Treatment for endometriosis depends on the severity of symptoms and the concern for fertility. Endometriosis in women without symptoms does not require treatment. In symptomatic women, it may be treated medically and/or surgically. Medical treatments include oral contraceptives GnRH agonists, progestin, and danazol. Limited conservative surgery may be indicated to remove the endometriosis while preserving the ovaries and fallopian tubes but the long-term success is limited. Hysterectomy and bilateral salpingo-oophorectomy is indicated in the presence of severe symptoms (especially intractable pain), when other treatments are unsuccessful and when pregnancy is no longer desired or possible (Lefebvre et al., 2002).

UTERINE PROLAPSE

Prolapse symptoms include a sensation of protrusion, pressure, urinary incontinence and rectal discomfort (Lefebvre et al., 2002). Stretching during childbirth, obesity or chronic cough may weaken the supporting ligaments and fascia.

Treatment may include pelvic floor exercises (Kegel exercises) and pessaries. Hysterectomy is indicated for more severe symptoms or advanced degrees of prolapse and may be combined with reconstruction of the pelvic supports and vaginal repair.

HYSTERECTOMY

Hysterectomy is described as a permanent solution for discretionary indications and has high patient satisfaction in properly selected patients. These patients are seen to be those women who have completed childbearing, have been informed of alternative therapies and have tried more conservative management without satisfactory results.

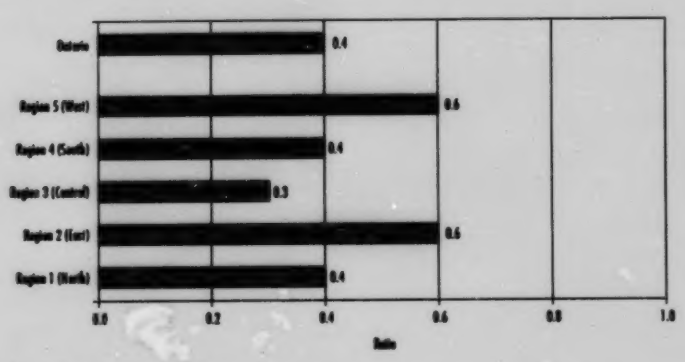
Vaginal hysterectomy should be considered as the first choice of surgical approach for most benign indications for hysterectomy (Ottosen et al., 2000) as it is associated with less morbidity and post-operative complications and has a faster recovery time than abdominal hysterectomy (Lefebvre et al., 2002). However, in 1999/2000 vaginal hysterectomies were only about half as common as abdominal hysterectomies across Ontario (Brown et al., 2001).

The laparoscopic approach to hysterectomy has advantages for women if it allows a hysterectomy to be performed vaginally that otherwise could have only been performed abdominally.

The removal of the ovaries in women under age 40 during hysterectomy (oopherectomy) for benign uterine conditions, other than endometriosis or a family history of ovarian cancer, is controversial and usually unwarranted. Overall, 72% of hysterectomies in Ontario in women under age 40 (excluding those performed for cancer, HIV or endometriosis) are total or included oopherectomy (Brown et al., 2001).

Exhibit 4

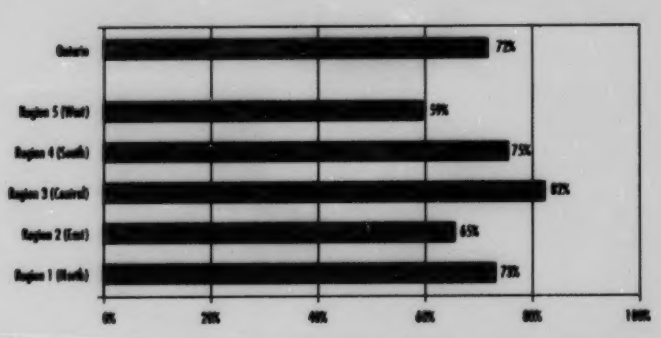
RATIO OF VAGINAL TO ABDOMINAL HYSTERECTOMIES, ONTARIO AND REGIONS, 1999/2000



Source: Brown et al., 2001

Exhibit 5

PERCENTAGE OF HYSTERECTOMIES THAT ARE TOTAL OR INCLUDE OOPHERECTOMY IN WOMEN LESS THAN 40 YEARS OLD, ONTARIO AND REGIONS, 1999/2000



Source: Brown et al., 2001

Availability of Services In Ontario

What do Women Want?

In keeping with the Terms of Reference for the Expert Panel on Best Practices in the Use of Hysterectomy, six two-hour discussion groups were conducted with English-speaking, Francophone and Aboriginal women in Northern Ontario in order to investigate:

- Where women get information regarding benign uterine conditions and hysterectomy, what they know about benign uterine conditions and hysterectomy, and what influences their treatment choices; and
- Whether women who have had hysterectomies were offered other types of care and if so, why they did not access these or find them acceptable.

Summary of Discussion Group Findings

There was consensus among discussion group participants that women in the North who suffer from benign uterine conditions would like to have access to additional information on all issues related to benign uterine conditions and hysterectomy. For example, women want to know what the alternatives to hysterectomy are, as well as what to expect after a hysterectomy (physical and emotional effects and sexuality), as this information is critical in making informed decisions about treatment. Women would like to access resources such as booklets, books and tapes through their family physicians' offices. Other information sources that would be valuable to Northern women include discussion/support groups, a health information telephone hotline and workshops/information sessions conducted by the local public health unit.

For most women in the discussion groups, quality of life was the most important factor in the decision to undergo a hysterectomy. Excessive bleeding (including resulting anemia) and pain had a profoundly detrimental effect on many aspects of their lives: work, relationships, social activities, and mental health.

Women in the discussion groups recognized that in Northern Ontario, there are an insufficient number of physicians to adequately address women's needs. For this reason, many physicians may not have time to fully discuss all treatment options with their patients. However, women feel that physicians should be familiar with all possible treatment options and should refer patients to other information sources (health unit, other health providers, web sites, and references) upon request or when indicated. Women support a model of care that allows physicians the time to provide comprehensive care.

Waiting times for family physicians and gynaecologists was cited as an important factor in the decision to undergo a hysterectomy, particularly in Sudbury. Because time between doctors' visits is long (months), experimenting with alternative treatments, which may not work, seemed risky to many women. Also, because of long waiting times to see a gynecologist and to subsequently schedule a hysterectomy, many women felt a sense of urgency to schedule the hysterectomy at their consultation.

Some women felt that their doctors had a propensity either for or against hysterectomy which they imposed upon their patients, thereby not allowing women an adequate role in treatment decision-making. Women who were more actively involved in the decision making process were more satisfied with their outcomes.

Discussion group participants made the following suggestions to improve care related to benign uterine conditions and hysterectomy for Northern women:

- Increased access to information resources;
- More information-sharing and open discussion with physicians;

- Access to female gynaecologists;
- The ability to obtain a second opinion;
- More visiting specialists from the South;
- A 1-800 number staffed by nurses trained in benign uterine conditions; and
- Support groups to share experiences with other women.

Discussion group participants perceived lower rates of hysterectomies in Southern Ontario as attributable to:

- Access to more physicians in general, and in particular access to more highly skilled/specialized physicians;
- Having the opportunity to get a second opinion; and
- Increased access to alternative therapies.

A Francophone discussion group identified additional issues faced by Francophone women in the North, including difficulty communicating with physicians due to language barriers, religious factors associated with contraception and organ removal, and societal taboos around sexuality and menopause.

The Francophone discussion group made the following suggestions for improving care related to benign uterine conditions and hysterectomy for Francophone women in the North:

- Access to an appointment with a Francophone nurse who could discuss benign uterine conditions, hysterectomy and menopause in French;
- Access to discussion groups/support groups in French to share experiences with others; and
- Information tools in French that are simplified and that explain medical terms clearly.

An Aboriginal discussion group identified additional issues faced by Aboriginal women in the North, including:

- Potential for emotional issues related to hysterectomy as a result of:
  - The role of family and childbearing in Aboriginal society;
  - The traditional native belief of 'keeping your body whole as the creator intended'; and
  - The increased prevalence of sexual abuse among Aboriginal women;
- Cultural beliefs about sexuality, and shyness/embarrassment in discussing medical conditions; and
- Fear of doctors and hospitals, which act as a barrier to patient empowerment and decision-making.

The Aboriginal discussion group made the following suggestions for improving care related to benign uterine conditions and hysterectomy for Aboriginal women in the North:

- Practitioner awareness of the potential for emotional sensitivity in relation to hysterectomy among Aboriginal women;
- Respect from health care providers for traditional Aboriginal views and practices concerning sexuality;
- Counseling for Aboriginal women prior to undergoing a hysterectomy, conducted by native people in native languages;
- Increased access to traditional healers;
- Health classes in schools where Aboriginal girls can develop awareness and openness about their body and a healthy level of self-esteem;
- Aboriginal women's support groups for information sharing and support.

See Appendix E for a summary of discussion group responses.

These focus group findings are consistent with research from the United States, Australia, New Zealand and Britain, and Dharmalingam and colleagues (2000) reported consistent findings in many other national studies. In addition, their research strongly supported the findings in other studies that higher education and occupational status was usually associated with a lower likelihood of hysterectomy. They concluded that this was because "Better-educated women 1) are more likely to seek medical advice and to be better informed about advantages and risks, 2) have greater access to information and resources, 3) communicate better with their doctors, 4) are more likely to seek alternative treatments, and 5) are more likely to be viewed as intelligent and knowledgeable by doctors." They suggest that the absolute rate of hysterectomy is not as important as the existing socio-political context that allows women to make well-informed decisions about their health and quality of life.

The Foundation for Informed Decision Making has developed numerous excellent shared decision making programs in video and interactive formats to provide evidence-based information on the options, risks and outcomes of therapies for many diseases and medical conditions, including fibroids and AUB. Patient testimonials are included in a non-judgmental presentation of treatment options. The video "Treatment Choices for Benign Uterine Conditions: Abnormal Bleeding" (1999) has been reviewed by a group of Ontario women; results can be found in Appendix F.

Patient education tools regarding hysterectomy, AUB and fibroids available to women in Ontario do not appear to be consistent or coordinated. Internet sites are numerous, but most are support groups that contain varying levels of accuracy and information. Some professional sites are available and are generally associated with women's health programs at hospitals. A search for 'hysterectomy' on the Health Canada web site did not reveal any patient centred information or links to other sites. The American College of Obstetricians and Gynecologists produces an informative series of patient education brochures that address specific subjects such as abnormal uterine bleeding, endometriosis, uterine fibroids, endometrial ablation, hysterectomy and laparoscopically assisted vaginal hysterectomy (e.g. American College of Obstetricians and Gynecologists 2000, 1999a, 1999b, 1998). These brochures are available to physician members at a moderate price for distribution to patients. Similar brochures are not available through the Society of Obstetricians and Gynecologists of Canada.

EDUCATION AND AVAILABILITY OF HEALTH CARE PROVIDERS

No greater demonstration of the challenge of Ontario's immense geography exists than in the disproportionate rates of health care providers, specifically in Northern and rural Ontario. Many communities are facing situations where any migration of population poses extreme burden on a system that has little elasticity. To demonstrate the severity of the situation, current data shows that in the Toronto District Health Council the rate of GP/FP (General/Family Practitioners) per 100,000 population is 116 and the specialist rate is 161. However, in the Algoma-Cochrane-Manitoulin and Sudbury District Health Council the GP/FP rate is 75 per 100,000 and the specialist rate is 59 (Statistics Canada, 2000). The latter rates reveal severe access barriers to health care, and have a significant impact on many aspects of the health professional's practice including access and ability to participate in continuing education and quality assurance. See Appendix G for full provincial data.

In a 2000 study, 92% of primary care physicians in Northern Ontario wanted to participate in continuing education programs, especially concerning abnormal uterine bleeding, but lack of local courses or accessible venues deterred many from participating (Vigod & Stewart, 2001). In the same study, 75% of the family physicians surveyed were not familiar with any Clinical Practice Guideline (CPG) for the management of AUB or benign conditions that might lead to hysterectomy and 63% did not know such guidelines existed.

Exhibit 6

CONTINUING MEDICAL EDUCATION: PHYSICIANS' DESIRED FORMAT

Format	N (%), N = 179
Copies of clinical practice guidelines	141 (78.8)
Tips for medical/hormonal management of AUB	90 (50.3)
Journal articles	69 (38.5)
Courses held locally	63 (35.2)
Pamphlets	38 (21.2)
Web-based	36 20.1)
Hands-on instruction (e.g. endometrial sampling)	33 (18.4)
Videotapes	27 (15.1)
Audiotapes	17 (9.5)
Telemedicine	17 (9.5)
Calendar charts for quantitative measurement of bleeding	17 (9.5)
Courses held at a medical school	15 (8.4)

***Source:** Vigod & Stewart, 2001*

Exhibit 7

PHYSICIANS' REASONS FOR NOT USING A CLINICAL PRACTICE GUIDELINE (CPG) FOR AUB OR HYSTERECTOMY

Deterrent	N (%), N = 177
I did not know that such a guideline existed	112 (63.3)
I am not familiar enough with the guideline	35 (19.8)
I am confident in managing abnormal uterine bleeding without a guideline	26 (14.7)
I don't have time to look through the guideline	9 (5.10)
I have searched, but was unable to find such a guideline	6 (3.40)
I never see cases of abnormal uterine bleeding	2 (1.10)
I do not agree with the guideline(s)	1 (0.60)
I do not believe in CPGs in general	1 (0.60)

***Source:** Vigod & Stewart, 2001*

An interesting inverse relationship exists in Canadian Institute for Health Information (CIHI)/ Ontario Physician Human Resource Data Centre (OPHRDC) data regarding physician to population ratios and hysterectomy rates. Hysterectomy rates for discretionary diagnosis including AUB are higher in areas where there is limited availability of gynaecologists. One conclusion is that under-serving this population of women leads to less acceptability of medical management, especially if there are long waiting lists for appointments, long distances to travel and/or inaccessibility of follow-up. In this situation, hysterectomy may be the only acceptable option for the patient.

There is an urgent need to increase the number of obstetricians/gynaecologists recruited and retained in the Province of Ontario. In 1999/2000, only 456 gynaecologists fit a billing profile of general gynaecology including medical and surgical management of abnormal uterine bleeding (Ministry of Health and Long-Term Care). In 1999 approximately 15% of obstetrician/gynaecologists practiced no general gynaecology. The OPHRDC has not provided data that reflects current attrition rates. The 1999/2000 Ontario attrition rate of practicing obstetricians/gynaecologist was 7% (Kralj, 2001), much higher than the Canadian Medical Association estimates of a maximum of 2% attrition rate per year. At this rate, 20% of the obstetricians/ gynaecologist work force is predicted to retire or leave Ontario within three years (Society of Obstetricians and Gynaecologists Human Resources Survey, 2000).

The Canadian Resident Matching Service (CaRMS) residency training matches show decreasing first choice matches for obstetrics and gynaecology residency positions and unfilled positions in Ontario. A simple increase in residency training positions will not increase the supply of Ontario gynaecologists, many of whom are close to retirement. Relevant groups need to work towards making obstetrics and gynaecology a more valued and attractive specialty for medical students.

Changing trends in human resources including attitudes, lifestyles and the rising proportion of female gynaecologists have resulted in a decrease in the hours that physicians, especially gynaecologists and obstetricians, are prepared to dedicate to the practice of medicine. These trends have to be understood and accounted for when planning human resources in obstetrics and gynaecology. It is predictable that practitioners will be less flexible in increasing their workload beyond what they are presently providing to meet the needs of an under-serviced population.

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Changing trends in human resources including attitudes, lifestyles and the rising proportion of female gynaecologists have resulted in a decrease in the hours that physicians, especially gynaecologists and obstetricians, are prepared to dedicate to the practice of medicine. These trends have to be understood and accounted for when planning human resources in obstetrics and gynaecology. It is predictable that practitioners will be less flexible in increasing their workload beyond what they are presently providing to meet the needs of an under-serviced population.

The problem is further escalated by the declining number of family practitioners practicing obstetrics thereby passing this workload to obstetrics and gynaecology specialists (Lofsky, 1998).

Evidence shows that almost 50% of nurse practitioners or RN(EC)s in Ontario are either not employed or under-employed as nurse practitioners (Caty, 2000). Even in the current situation of severe health care shortages, barriers exist which impede the primary health care nurse practitioner's ability to effectively participate within the system. Physicians and RN(EC)s are trained independently of one another at the undergraduate and postgraduate level (Pringle et al., 2000), impeding the full development of collaborative practice. Another barrier includes the lack of legal authority to order cytological examination once an endometrial biopsy has been performed, even though assessment of AUB is within the legal scope of practice for the RN(EC) (Laboratory and Specimen Collection Centre Licensing Act, 1998). There continues to be a lack of remuneration mechanisms for nurse practitioners to work with physicians in group practices, especially physicians who are reimbursed through fee-for-service. Finally, there is no mechanism in place which enables an RN(EC) to refer and/or consult with specialists, even though these aspects of RN(EC) practice are legally embedded in nursing legislation (College of Nurses of Ontario, 1998; Nursing Act, 1991), which contains procedural and clinical expectations for consultations and referrals.

RECOMMENDATIONS

The Expert Panel on Best Practices in the use of Hysterectomy believes that the management of benign uterine disorders is a complex, multi dimensional process requiring accurate information and education for the woman as well as the practitioner. Aspects of these disorders may affect every segment of a woman's life, yet for many it remains a problem that is not openly discussed or addressed. The very intimate nature of this disease has promoted the silence. Advancements in treatment, both surgical and non-surgical, are now available, but in many areas of Ontario these services are limited or non-existent. All women in Ontario, regardless of age, race, culture, language, socioeconomic status, sexual orientation and geography must have access to the best practices in the management of the discretionary indications for hysterectomy. This remains our vision.

Accordingly, the Expert Panel has developed the following recommendations to improve care related to benign uterine conditions and promote the appropriate use of hysterectomy in Ontario:

PATIENT EDUCATION, SATISFACTION AND QUALITY OF LIFE

1. Develop and disseminate a range of accurate information and decisional support tools for women about conditions and treatment options related to benign uterine conditions that are linguistically and culturally appropriate.

   Topics must include:

   i. Normal and abnormal menstrual periods, abnormal inter-menstrual bleeding, fibroids, chronic pelvic pain, endometriosis, uterine prolapse, urinary incontinence, menopause, and measurement tools for uterine bleeding.

   ii. Investigational procedures such as hysteroscopy, laparoscopy, vaginal ultrasound, endometrial biopsy, and dilatation and curettage.

   iii. Treatment options such as medical treatments, ablation therapies, hysteroscopy, embolization, myomectomy and various types of hysterectomy.

   iv. Indications, limitations, and possible complications and outcomes of all treatments.

   Information formats must:

   i. Include pamphlets, media coverage, decision-making kits, videotapes, audiotapes, internet, Telehealth, support groups, and workshops and symposia.

   ii. Be available from multiple sources including family doctors, gynaecologists, nurse practitioners, public health nurses, health centres, pharmacies and community health centres.

   iii. Be written at grade 6 literacy level and available in English, French and other major languages of the health district.

2. Correct through education the misperception in some areas that hysterectomy is a normal and desirable event after childbearing is completed.

3. Consider the challenges to Northern and rural/remote Ontario women which include a shortage of family doctors, gynaecologists and nurse practitioners as well as the barriers imposed by geography (distance, roads, weather), literacy, economics and lack of alternative medical equipment.

   i. Develop regional women's health centres in the north and provide care and equipment to treat high priority women's health problems including gynaecological conditions.

   ii. Include education and decisional supports for benign uterine conditions in the Ontario Mandatory Health Programs and Service Guidelines by linking the reproductive health, sexual health and chronic disease prevention programs and ensuring adequate funding for implementation.

   iii. Enhance the visiting specialist program for gynaecologists in the North and adequately reimburse the program in order to attract participants.

   iv. Continue travel grants for patients to visit specialists.

4. Provide resources to address psychosocial issues related to benign uterine conditions (e.g. depression, anxiety, relationship issues, fertility, sexuality, and abuse) through education, professional evaluation, counseling and support groups before, during and following treatment.

5. Ensure through drug subsidies that all women have equal access to hormonal treatments for abnormal uterine bleeding.

EDUCATION AND AVAILABILITY OF HEALTH CARE PROVIDERS

TRAINEES

6. The Council of Ontario University Programs in Nursing (COUPN) and the Council of Ontario Faculties Medicine (COFM), in consultation with other appropriate organizations, develop an information and education plan for undergraduates and postgraduates to promote mutual understanding of roles between health care professions.

7. Ontario's medical schools, in collaboration with the Ontario and federal governments, continue to take steps to develop rural medical education at the undergraduate and post graduate level.

8. Ontario's education programmes for nurse practitioners, in collaboration with the Ontario and federal governments, continue to provide educational opportunities to prepare Registered Nurses in the Extended Class (RN(EC)s) to work in rural communities.

9. Emphasize the diagnosis and management of abnormal uterine bleeding in the core curriculum for nurse practitioners and family practitioners including:
   i. Endometrial biopsy.
   ii. Medical management of abnormal uterine bleeding.

10. Emphasize training in hysteroscopy and hysteroscopic procedures for postgraduates in gynaecology.

PRACTITIONERS

11. Develop, in conjunction with the relevant professional organizations, continuing education (CE) initiatives in a range of formats for the diagnosis and management of benign uterine disorders.

12. Develop a 'toolkit' that includes products that increase knowledge (e.g. guidelines) but also enable best practice (e.g. consumer information and decision aids, awareness of local resources, algorithm, etc.). The toolkit must be bundled with an academic outreach initiative (e.g. CE, academic detailing, etc.) and preferably evaluated.

13. Assist practitioners in rural and remote areas through funding and locums to attend continuing education events.

14. Develop and support preceptor programs including clinical traineeships for individual practitioners to learn and/or upgrade:
   i. Diagnostic skills and management protocols for benign uterine conditions.
   ii. Vaginal hysterectomy and laparoscopic techniques for hysterectomy.

AVAILABILITY AND UTILIZATION OF HEALTH CARE HUMAN RESOURCES

15. Review and revise the approved list of laboratory tests for RN(EC)s to include the ordering of pathology examination of endometrial biopsies.

16. Promote the utilization of RN(EC)s in Ontario by enabling all physicians, including fee-for-service physicians, to work with RN(EC)s, through appropriate incentives and compensation.

17. Develop innovative recruitment, retention and replacement strategies for family physicians, RN(EC)s and specialists for under-serviced communities.

18. Establish appropriate compensation for medical specialists to provide referral and consultation support for RN(EC)s.

19. Address the alarming attrition rate of obstetricians and gynaecologists.

20. Provide incentives to family practitioners to repatriate them to the practice of low risk obstetrics.

21. Develop a model of comprehensive, integrated well woman care that is accessible to all women in Ontario.

MEDICAL AND SURGICAL MANAGEMENT OF BENIGN UTERINE CONDITIONS

22. Make hysteroscopic and global endometrial ablation procedures more widely available to women throughout Ontario by designating funding and situating these procedures in outpatient centers and ambulatory surgical facilities.

23. Encourage the use of the most clinically appropriate route of hysterectomy through various strategies including the development of a decision tree and preferential reimbursement, recognizing the expertise and time required to perform these surgeries.

24. Consider including saline sonohysterography in the Ontario Physician Schedule of Benefits. (Note: included as of April 1, 2002.)

RECOMMENDATIONS FOR FUTURE RESEARCH

25. Commission research to evaluate:

    i. Quality of life issues for women with benign uterine conditions.

    ii. Availability and acceptability of information and decision-making aids related to treatment for benign uterine conditions.

    iii. Patient satisfaction and outcomes with various treatment options for benign uterine conditions, including endometrial ablation as an alternative to medical management in the treatment of abnormal uterine bleeding.

    iv. Clinical trials of new and emerging technologies for endometrial ablation and the treatment of fibroids including efficacy, short and long-term risks and benefits.

APPENDIX A – EXPERT PANEL AND WORKING GROUPS

MICHAEL EVANS, MD, CCFP

Dr. Michael Evans is a staff physician and runs a busy inner-city practice at the Department of Family and Community Medicine (DFCM) at the University Health Network – Western Division. He is an Assistant Professor in the DFCM at the University of Toronto, a Research Scholar at the Family Healthcare Research Unit, and Principal Investigator in the new Knowledge Translation Program at the University of Toronto.

GISÈLE HENDERSON, REGN, PHN, BSCN

Gisèle Henderson is Program Coordinator for the sexual health and reproductive health programs of the Sudbury and District Health Unit, Health Promotion Division. She received her bilingual diploma in Nursing from Cambrian College School of Nursing, and her Bachelor of Nursing Science from Laurentian University. Gisèle is involved in several projects whose goals are to work with communities to promote and protect health and to prevent diseases. In 2000, she coordinated Sudbury's first "Lady In Red: The Woman in You" symposium on benign uterine conditions.

ROSELLA M. KINOSHAMEG, REGN, BSCN

Rosella M. Kinoshameg is Odawa/Ojibway, and is a member of the Wikwemikong Unceded Indian Reserve, Manitoulin Island. She is a Registered Nurse and received a Doctor of Sacred Letters, Honoris Causa (1996) from Regis College, University of Toronto. Rosella has over fifteen years experience of working with First Nations communities in Community Health as a Community Health Nurse, and Manager/Educator. She has served as board member of Manitoulin Health Centre Board of Directors for twelve years, three of these as Chair of the Board. Presently, she is a member of the Cancer Care Ontario Regional – North East Council, and serves as Vice President for the Aboriginal Nurses Association of Canada.

GUYLAINE LEFEBVRE, MD, FRCSC, FACOG

Dr. Guylaine Lefebvre is an Associate Professor at the University of Toronto. She is Chief of Obstetrics and Gynecology at St. Michael's Hospital and Chair of the Clinical Practice Committee for the Society of Obstetricians and Gynecologists of Canada. She is also a Member of the Ontario Women's Health Council.

NICHOLAS A. LEYLAND, BASC, MD, FRCSC

Dr. Nicholas A. Leyland is Head of Gynaecology at Mount Sinai Hospital and is an Assistant Professor of Obstetrics and Gynecology in the Dept of Obstetrics and Gynecology, Faculty of Medicine, University of Toronto. He is an endoscopic surgeon.

JOHANNE MOUSSEAU, RN(EC), MSC

Johanne Mousseau is an Assistant Professor at McMaster University's School of Nursing and teaches in the Primary Health Care Nurse Practitioner Programme. She is a Nurse Practitioner who has been involved in providing women's health services for over 25 years. Johanne is the Past Chair of the Nurse Practitioners' Association of Ontario. She was the Nursing Consultant for the Nurse Practitioner Initiative at the Ministry of Health from 1994-96 and assisted in moving the NP agenda forward. She continues to maintain a clinical practice in Toronto.

MELISSA NUTIK, BSC, MD, CCFP

Dr. Melissa Nutik is a Lecturer in the Department of Family and Community Medicine, University of Toronto and is Associate Staff in the Department of Family and Community Medicine, University Health Network. She is also Active Staff at both the St. George Health Centre and The Bay Centre for Birth Control, and is a Clinical Associate at The Charlotte and Lewis Steinberg Familial Breast Cancer Clinic, North York General Hospital.

TERRY O'DRISCOLL, MD, CCFP

Dr. Terry O'Driscoll is a member of the Active Staff of the Sioux Lookout District Health Centre. She is a Fellow of the Canadian College of Family Physicians and a graduate of McMaster University Medical School. Dr. O'Driscoll is active in Family Practice in the remote community of Sioux Lookout and has a special interest in women's health.

JERRY SHIME, MD, FRCSC, MSc

Dr. Jerry Shime is a Professor of Obstetrics and Gynaecology in the Department of Obstetrics and Gynecology, Faculty of Medicine, University of Toronto. He is the former Obstetrician and Gynaecologist in Chief, Women's College Hospital (1986-1999). He is a member of the Canadian Medical Association, the Ontario Medical Association, the Society of Obstetricians and Gynaecologists of Canada and the International Menopause Society.

DONNA E. STEWART, MD, FRCPC (CHAIR)

Dr. Donna E. Stewart is Professor and Lillian Love Chair in Women's Health, University Health Network and University of Toronto. She is a researcher, educator, clinician and policy advisor on women's health, and a Member of the Ontario Women's Health Council.

JANICE WILLETT, MD, FRCSC

Dr. Willett is a practicing gynaecologist in Sault Ste. Marie and Medical Director of the Surgical Program and Maternal Child Program at the Sault Area Hospitals. She has represented the Obstetricians and Gynaecologists of Ontario for three years as Chair. She is a member of the OMA Board of Directors as Surgical Assembly Representative and OMA District 9 Chair. Dr. Willett was born and raised in Elliot Lake and following university chose to return to Northern Ontario to practice medicine and raise her family.

APPENDIX B – GLOSSARY

Clinical Practice Guidelines (CPG) Guidelines and protocols established by professional bodies reflecting emerging clinical and scientific advances.

Bilateral Salpingo-oophorectomy Removal of the both ovaries and fallopian tubes.

Dilatation and Curettage (D&C) A procedure in which the cervix is opened and tissue is scraped or suctioned from the lining of the uterus.

DHC District Health Council: An advisory council to the Minister of Health established in each distinct health region throughout the Province of Ontario.

Endometrial ablation Removal of the lining of the womb (endometrium).

Hysteroscopic Utilizing a thin telescope-like device that is inserted into the uterus through the vagina and cervix.

Kegel Exercises Pelvic muscle exercises that assist in bladder and bowel control.

Laparoscopy A surgical procedure in which a slender, light transmitting instrument (laparoscope) is used to view the pelvic organs or perform surgery.

Laparotomy A surgical procedure in which an incision is made in the abdomen.

Nonmalignant Referring to a non-cancerous state (in this document).

Pessary device worn in the vagina to support the uterus.

RN(EC) Registered Nurse, Extended Class: A Registered Nurse who has successfully completed the Primary Health Care Nurse Practitioner Programme that is offered by a consortium of ten university schools of nursing. The programme began in September of 1995. The title 'Extended Class' is a protected title of the College of Nurses of Ontario. As well as the controlled acts authorized to nursing in the Nursing Act (1991), RN(EC)s have authority to communicate a diagnosis, order ultrasound and prescribe a defined range of drugs. They may also order specific X-Rays and laboratory tests.

Saline Sonohysterography A transvaginal ultrasound that uses 15 ml of saline introduced into the uterine cavity to improve the diagnosis of intrauterine masses.

Transvaginal Ultrasound An ultrasound that is accomplished by placing the transducer (sound wave generator) in the vagina.

Ultrasound A test in which sound waves are used to examine internal structures.

Appendix C – Levels of Evidence

Quality of Evidence

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferable from more than one centre or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940's) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

Classification of Recommendations

A: There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.

B: There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.

C: There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.

D: There is fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

E: There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

Adapted from the Canadian Task Force on the Periodic Health Examination, as cited in Woolf et al., (1990).

APPENDIX D – SUMMARY OF INTERVIEWS WITH CHIEFS OF GYNAECOLOGY

STRATEGIES TO REDUCE HYSTERECTOMY RATES

Interviews were conducted with chiefs of gynecology in the five areas of Ontario (Hastings and Prince Edward, Waterloo, Halton, Simcoe and Algoma) in which hysterectomy rates showed the greatest decreases between 1994/95 and 1998/99. Most areas had more than one hospital which performed hysterectomies, but the chief of gynecology was either a jointly appointed chief, or knowledgeable about the sister hospitals' practices and procedures. Seven topics emerged as important strategies in the reduction in hysterectomy rates in these areas:

Staff Changes All five chiefs reported that they had a significant reduction in the numbers of older gynecologists who had either retired or moved during this interval, and who were perceived as having high hysterectomy rates. All five chiefs reported replacing these older gynecologists with younger ones, and three appointed more women staff, who they perceived as performing fewer hysterectomies.

Medical Management Four chiefs reported an effort to increase medical management of abnormal uterine bleeding. One reported an informal agreement among practitioners that patients would undergo two courses of medical management before consideration for surgery. Another requested that practitioners document medical therapy on the chart before patients were scheduled for surgery. One gynecologist-in-chief cited the high use of Depo-Provera in his department as being a factor in reduction of hysterectomy rates.

New Technologies Gynecologists-in-chief reported increased use of balloon and laser endometrial ablation (five centres), hysteroscopy (two centres) and laparoscopic surgery (two centres), which they felt were partly responsible for the significant reduction in hysterectomies.

Professional Education Three chiefs reported arranging continuing medical education including grand rounds, invited presentations by experts, preceptorships and peer teaching on medical and new technology alternatives to hysterectomy.

Patient Education Four chiefs commented that better patient information results in a greater willingness for women to participate in informed medical decision making. The impact of patient presentation, expectation and knowledge was discussed, and they felt that patients who had a catastrophizing style of symptom presentation and a clear expectation that they wanted a hysterectomy were usually successful in their quest. Women who had both family and friends who had had hysterectomies often perceived it to be the only answer. Two chiefs reported that "some patients seemed to love the alternatives when they are presented," but that this was a very time-consuming and labour-intensive undertaking in a busy office.

Primary Care Management of Abnormal Uterine Bleeding Two chiefs reported that family doctors were now more likely to perform endometrial biopsies in their offices and to try birth control pills or non-steroidal anti-inflammatories before referring to gynecologists. They felt this was very appropriate and a better use of specialist gynecologic time.

Quality Assurance Four chiefs reported on quality assurance initiatives that may have contributed to a reduction in rates. Two of these conducted regular chart reviews of patients undergoing hysterectomy, and one reported a critical external review that had resulted in changes in practice, including the loss of privileges of a problematic practitioner.

The five gynecologists-in-chief were extremely helpful in giving their perspectives and they expressed interest in the Expert Panel proceedings and final report.

Donna E. Stewart, MD, FRCPC

Appendix E – Summary of Discussion Groups

Introduction

The purpose of the discussion groups was to obtain feedback and perspectives from Northern women on issues related to benign uterine conditions (e.g. abnormal uterine bleeding, fibroids, pelvic pain, and endometriosis) and hysterectomy.

Six two-hour discussion groups were held:

Thunder Bay Women who had a hysterectomy in the last five years for reasons other than cancer.

Thunder Bay Women currently considering a hysterectomy for reasons other than cancer.

Thunder Bay Aboriginal women who had a hysterectomy in the last five years or were currently considering a hysterectomy for reasons other than cancer.

Sudbury Women who had a hysterectomy in the last five years for reasons other than cancer.

Sudbury Women currently considering a hysterectomy for reasons other than cancer.

Sudbury Francophone women who had a hysterectomy in the last five years or were currently considering a hysterectomy for reasons other than cancer.

It should be noted that in addition to the Francophone discussion group, approximately half of the participants in the other two Sudbury discussion groups were Francophone, but chose not to attend the French discussion as they were more comfortable discussing their medical condition in English.

The large majority of the participants were between the ages of 37 – 57 years, and were married with two or more children. Most women lived in either Thunder Bay or Sudbury or in surrounding towns (e.g. Val Caron), though some participants were from more rural or remote communities (Birch Island, Timmins, and Windy Lake). Income and education levels varied between groups: most participants in Thunder Bay had completed a postgraduate degree and had an annual household income of at least $40,000, while most participants in Sudbury cited high school as the highest educational degree completed and had an annual household income of $20,000 – $40,000. In the Francophone discussion group, the majority of participants had completed part or all of a college or university degree, and annual household income was equally dispersed across income levels.

Summary of Responses

What do you consider "excessive" bleeding"?

Women defined excessive bleeding as near constant bleeding or excessively heavy bleeding which may include heavy clots and may result in other health problems such as anemia.

Where do you obtain gynaecology related information?

Whereas participants in Thunder Bay reported obtaining information from their gynaecologist and from the Internet and health magazines, participants in Sudbury reported obtaining information primarily from word of mouth (family, friends and coworkers), and from personal research using the internet, library and women's magazines (e.g. Chatelaine). Participants in Sudbury noted that they didn't get information from doctors because they didn't have time to ask questions during an office visit.

Which do you think is the most reliable?

Information sources such as the internet and books were considered to be reliable. It was noted that talking to people about gynecological concerns was often confusing as people give contradictory advice and have contradictory experiences. Furthermore, other people's prejudices for or against hysterectomy may influence a listener's opinions.

Is the information you obtain useful, easy to understand and easy to get? If not, what are the barriers?

Participants reported that the patient information that does exist is straightforward; however, there is not enough patient information available, and it is not always easily accessible. The main barrier to accessing information was lack of knowledge about what information is available and how/where to access it.

Do you think that more information would be helpful in making an informed decision about hysterectomy? If so, what information would you like to have?

Nearly all participants agreed that more information would be needed in order to make informed decisions about benign uterine conditions and hysterectomy. Participants would like information on nearly all aspects of benign uterine conditions and hysterectomy, specifically:

- A tool to quantify bleeding;
- Information on alternatives to hysterectomy such as drugs, hormones, and less invasive surgery;
- Information on surgical menopause and what to expect after a hysterectomy (including the physical and emotional effects of a hysterectomy, and sexuality after hysterectomy); and
- Decision aids for hormone replacement therapy, hysterectomy, and whether to have a full or partial hysterectomy, vaginal vs. abdominal hysterectomy, whether to have ovaries retained.

Where should this information be coming from?

Participants responded that resources such as tapes, booklets and/or books should be available at family physicians' offices. These resources should include a glossary of terms, diagrams, and a reference list for further reading. It was also noted that physicians should be able to refer their patients to additional information sources (e.g. web sites, references) upon request. It was suggested that nurses could provide information while patients are in the waiting room. Other suggestions of valuable information sources included discussion/support groups, a health information telephone hotline and workshops/information sessions conducted by the local public health unit.

What symptoms led to the diagnosis of your condition?

The large majority of participants reported that heavy bleeding and/or pain were the predominant symptoms which led to their initial diagnosis. Most were subsequently diagnosed with abnormal uterine bleeding, fibroids or endometriosis.

How did these symptoms affect your life?

Almost all participants reported that their symptoms had a profound negative effect on their quality of life. Their symptoms affected many areas of their lives such as mood, work, family, relationships, social activities and sexual function. Heavy bleeding often resulted in extreme fatigue. Many women reported a loss of self esteem, and several women reported becoming depressed as a result of having to cope with their condition.

Did you do anything about your symptoms until you went to the doctor (herbal medicine, Chinese medicine, etc.)?

The majority of women did not try alternative medicine for their symptoms.

Did you discuss your physical or emotional health with anyone other than a medical care provider? Why/why not?

Most participants reported speaking to family, friends and/or coworkers about their condition. As previously mentioned, participants felt talking to people was often confusing as they received contradictory advice and heard about contradictory experiences. Furthermore, they were influenced by other people's prejudices for or against hysterectomy. Women reported being embarrassed to talk about their condition.

Did you visit your doctor prepared to have a hysterectomy? Did you request a hysterectomy?

Women who had been dealing with their condition for a prolonged period (years) were prepared to have a hysterectomy, although few actually requested it. Women who had not been

dealing with their condition for a prolonged time were surprised by the proposal of a hysterectomy.

Do you feel comfortable talking to your doctor about your gynecological concerns? If not, what makes you uncomfortable?

Overall women felt very comfortable as long as their gynecologist/family doctor was open to discussion. Women reported that it was very important to have a physician who was open to discussing the emotional aspects (e.g. effect on body image) of undergoing a hysterectomy. A support network for hysterectomy and/or surgical menopause was also suggested.

Did/do you have any fears related to undergoing a hysterectomy? If so, what were they?

The most commonly reported fears were loss of sexual function and impact on relationship with husband, as well as complications from surgery, cancer, and decreased body image (e.g. "I wouldn't feel like a complete woman").

Did/do you feel pressured into having/not having a hysterectomy? If so, by whom?

In almost all cases women reported that their doctor made their treatment decision, be it to have a hysterectomy or to try a medical or surgical alternative. Some women felt indirectly pressured into a treatment option by not being given complete information. Women reported that their husbands/partners were generally supportive, and left the decision making to them.

Do you know of any alternatives to hysterectomy?

Many discussion group participants cited hormone replacement therapy (HRT) and dilatation and curettage (D & C) as alternatives to hysterectomy. Many women had undergone multiple D & Cs, and perhaps as a result there was a misconception that D & C was a treatment rather than a diagnostic tool. Some women were also aware of watchful waiting. Very few women were aware of any surgical alternatives to hysterectomy. Virtually none of the participants in the Thunder Bay groups were aware of any alternatives to hysterectomy.

Have you tried any options/alternatives? If so, which one(s)?

Most discussion group participants had had at least one D & C, and many had undergone multiple D & Cs. Some had tried, or were currently taking, HRT. Two women had undergone endometrial ablation; one had been told to have it by her doctor, while the other researched it herself and requested it from her doctor. In both cases, hysterectomy was eventually performed.

What were the most important factors that made you decide to undergo a hysterectomy?

Most women agreed that quality of life was by and large the most important factor in the decision to undergo a hysterectomy. Waiting times for family physicians and gynecologists was also cited as an important factor, particularly in Sudbury. Women reported that by the time they were able to see a gynecologist, they were already having difficulty coping with their condition. Furthermore, they feared that if they didn't schedule the hysterectomy right away, they would face longer wait times (several month wait to get another appointment with a gynecologist, and subsequent wait to have a hysterectomy), which they would not be able to cope with if their condition worsened.

When you decided to have a hysterectomy, were you sure about it or did you have any hesitation?

Women that had tried other options and had been coping with their condition for a prolonged time were very sure about having a hysterectomy. Women who had not been dealing with their condition for a prolonged time had more reservations about having a hysterectomy. It should be noted that the large majority of participants did not feel that they had decided to have a hysterectomy; rather, the decision had been made by their gynaecologist.

At the time of your decision, how satisfied were you with your and your physician's roles in the decision-making process?

Most women reported that their physicians made their treatment decisions, and were dissatisfied with this.

Do you now think that the surgery you underwent was the best solution to your problem?

Most women who had a hysterectomy felt that it had been the best solution to their problem. However, some women did express regret about having a hysterectomy as they felt it had not been necessary.

Did you feel you were adequately prepared for how you felt after the hysterectomy?

Most women reported that very little information was provided to them on what to expect after a hysterectomy, and thus they were largely unprepared for the physical and/or emotional effects of hysterectomy.

What would make/would have made your experience easier?

Most women reported that more information resources, as well as more frequent information-sharing and open discussion with physicians, would have made their experience easier. Many women also responded that a female gynaecologist that could relate to these types of problems would have been preferable. Other responses included the ability to obtain a second opinion, more visiting specialists from the South, a 1-800 number staffed by nurses trained in benign uterine conditions, and support groups to share experiences with other women.

What issues do you feel physicians should be aware of when treating women for the gynaecological concerns discussed today?

Some women noted that doctors don't take heavy bleeding and pain seriously and simply attribute them to bad menopause. Thus, they recommended that physicians be made aware that abnormal bleeding and pain are legitimate problems, and that women who present with these symptoms are not being overly headstrong, demanding or hysterical.

You may be aware that there is a difference between Southern and Northern Ontario in the rate of hysterectomies performed. Why do you think this difference exists?

Nearly all participants agreed that the rate of hysterectomies is lower in Southern Ontario because women there have:

- Access to more physicians in general, and in particular access to more highly skilled/specialized physicians;
- Opportunities to get a second opinion; and
- Increased access to alternatives.

Women felt that because of physician shortages, physicians in Northern Ontario "don't have time to take good care of you". Women also noted that because of long waiting times, there is an attitude in Northern Ontario that "you better take it when you can". Other reasons discussed included lack of patient education and the use of hysterectomy as a contraceptive practice.

Overall, in situations where hysterectomy is a viable therapy, what role should the physician, patient and, if appropriate, partner each play?

There was a strong consensus that women should be the decision-makers, although most women felt that this wasn't the case in their own situation.

Appendix F – Patient Information & Education

List of Products Reviewed

American College of Obstetricians and Gynecologists

409 12th Street, SW, PO Box 96920, Washington DC, 20090-6920 (http://www.acog.org)

1. Abnormal Uterine Bleeding
2. Understanding Hysterectomy
3. Laparoscopy
4. Endometrial Hyperplasia
5. Dilation and Curettage (D&C)
6. Important Fact About Endometriosis
7. Hysteroscopy
8. Uterine Fibroids
9. Laparoscopically Assisted Vaginal Hysterectomy
10. Endometrial Ablation

Health Dialog Inc.

1750 Elm Street, Manchester, New Hampshire, 03104. Phone (603) 627-6975 (http://www.healthdialog.com)

Shared Decision-Making Library

1. Benign Uterine Conditions – Abnormal Uterine Bleeding
2. Benign Uterine Conditions – Fibroids

Available but not reviewed by the Expert Panel

3. Hormone Replacement Therapy
4. Ovarian Cancer
5. The Informed Health Consumer
6. Treating Your Breast Cancer – Adjuvant Therapy
7. Treating Your Breast Cancer – Surgery Decision

WOMEN'S HEALTH SYMPOSIUM (AUB VIDEO REVIEW)

On November 14, 2001, the University Health Network held a Women's Health Symposium on Abnormal Uterine Bleeding. As part of the symposium, the video "Treatment Choices for Benign Uterine Conditions: Abnormal Bleeding" (Foundation for Informed Decision-Making, 1999) was shown. Participants were given a questionnaire to complete; attached is a summary of responses.

From whom do you get information about gynecological problems such as abnormal uterine bleeding?

	N (%)
Obstetrician/gynaecologist	17 (81%)
Family doctor	14 (66.7%)
Nurse	4 (19%)
Friends	4 (19%)
Family	2 (9.5%)
Other	2 (9.5%)

Who is the most reliable source for you to get information about abnormal uterine bleeding?

	N (%)
Obstetrician/gynaecologist	17 (81%)
Family doctor	13 (61.9%)
Nurse	4 (19%)
Family	1 (4.8%)
Other	1 (4.8%)
Friends	0

Which is the easiest way for you to get information about this issue?

	N (%)
Magazines/newspapers/books/ pamphlets	16 (76.2%)
Internet	8 (38.1%)
Audio-videotape	4 (19%)
TV/radio	2 (9.5%)
Other	2 (9.5%)

Would more information be helpful in learning how to manage abnormal uterine bleeding?

	N (%)
Yes	17 (85%)
No	3 (15%)

How would you like to get more information about this topic?

	N (%)
Pamphlet	12 (57.1%)
Information seminar	11 (52.4%)
Website by reliable sponsor	7 (33.3%)
Video/DVD	6 (28.6%)
Decision-making tool	2 (9.5%)

What are the barriers to getting good information about this issue?

	N (%)
Doctor too rushed	11 (52.4%)
Hard to find	7 (33.3%)
Uncertain about reliability	5 (23.8%)
Language too difficult	1 (4.8%)

Who (doctor or woman) should ideally decide whether or not to have a hysterectomy?

	N (%)
Woman alone	1 (4.8%)
Mostly woman	8 (38.1%)
Equally shared	12 (57.1%)
Mostly doctor	0
Doctor alone	0

How much information in the video you saw today was new to you?

	N (%)
1 – None	2 (10%)
2	6 (30%)
3	3 (15%)
4	4 (35%)
5 – All	2 (10%)

What information in the video was new to you?

- Ablation (6)
- Treatment options other than surgery (2)
- Sub-total hysterectomy (1)
- Treatment options (ablation, hysteroscopy, new drugs) (1)
- Simpler treatment e.g. laparoscopy, ablation. Certain conditions are benign (1)
- Not necessarily associated with cancer and fibroids (1)
- Medical options (1)
- After surgery (1)
- Instruments used (1)
- Statistics, results of research (1)

WOMEN'S HEALTH SYMPOSIUM (AUB VIDEO REVIEW)

On November 14, 2001, the University Health Network held a Women's Health Symposium on Abnormal Uterine Bleeding. As part of the symposium, the video "Treatment Choices for Benign Uterine Conditions: Abnormal Bleeding" (Foundation for Informed Decision-Making, 1999) was shown. Participants were given a questionnaire to complete; attached is a summary of responses.

From whom do you get information about gynecological problems such as abnormal uterine bleeding?

	N (%)
Obstetrician/gynaecologist	17 (81%)
Family doctor	14 (66.7%)
Nurse	4 (19%)
Friends	4 (19%)
Family	2 (9.5%)
Other	2 (9.5%)

Who is the most reliable source for you to get information about abnormal uterine bleeding?

	N (%)
Obstetrician/gynaecologist	17 (81%)
Family doctor	13 (61.9%)
Nurse	4 (19%)
Family	1 (4.8%)
Other	1 (4.8%)
Friends	0

Which is the easiest way for you to get information about this issue?

	N (%)
Magazines/newspapers/books/ pamphlets	16 (76.2%)
Internet	8 (38.1%)
Audio-videotape	4 (19%)
TV/radio	2 (9.5%)
Other	2 (9.5%)

Would more information be helpful in learning how to manage abnormal uterine bleeding?

	N (%)
Yes	17 (85%)
No	3 (15%)

How would you like to get more information about this topic?

	N (%)
Pamphlet	12 (57.1%)
Information seminar	11 (52.4%)
Website by reliable sponsor	7 (33.3%)
Video/DVD	6 (28.6%)
Decision-making tool	2 (9.5%)

What are the barriers to getting good information about this issue?

	N (%)
Doctor too rushed	11 (52.4%)
Hard to find	7 (33.3%)
Uncertain about reliability	5 (23.8%)
Language too difficult	1 (4.8%)

Who (doctor or woman) should ideally decide whether or not to have a hysterectomy?

	N (%)
Woman alone	1 (4.8%)
Mostly woman	8 (38.1%)
Equally shared	12 (57.1%)
Mostly doctor	0
Doctor alone	0

How much information in the video you saw today was new to you?

	N (%)
1 – None	2 (10%)
2	6 (30%)
3	3 (15%)
4	4 (35%)
5 – All	2 (10%)

What information in the video was new to you?

- Ablation (6)
- Treatment options other than surgery (2)
- Sub-total hysterectomy (1)
- Treatment options (ablation, hysteroscopy, new drugs) (1)
- Simpler treatment e.g. laparoscopy, ablation. Certain conditions are benign (1)
- Not necessarily associated with cancer and fibroids (1)
- Medical options (1)
- After surgery (1)
- Instruments used (1)
- Statistics, results of research (1)

I found the language in this video to be:

	N (%)
1- Too easy	1 (4.8%)
2	1 (4.8%)
3- Just right	15 (71.4%)
4	4 (19%)
5– Too complicated	0

The amount of information provided was:

	N (%)
1– Not enough	0
2	1 (4.8%)
3– Just right	16 (76.2%)
4	3 (14.3%)
5– Too much	1 (4.8%)

What extra information, if any, would you have liked to see in this video?

- Treatments for younger women (3)
- Defining AUB, showing diversity of Ontario population, attaching booklet summarizing video (1)
- Some tests that are done to determine nature of the bleeding (1)
- Taped surgical procedures (1)

How helpful would this video be in making treatment decisions?

	N (%)
1– Not helpful	0
2	0
3	3 (14.3%)
4	10 (61.9%)
5– Very helpful	8 (38.1%)

What aspects of this video would be particularly helpful in making treatment decisions?

- Treatment options (7)
- Knowing the options so that you can have input in the treatment option (2)
- Elaboration of options (1)
- Limited surgery treatments, side effects (1)
- Non-surgical options (1)
- Pros and cons of surgery (1)
- Effects of surgery (1)
- Clear explanation on when, how treatment needed, pros and cons of options (1)

- Information about risks, recovery times (1)
- Information about indications, side effects, risks and results of research (1)
- The whole video (1)

These videos would be most helpful if:

	N (%)
They could be discussed with a family doctor	14 (66.7%)
They could be discussed with a gynecologist	13 (61.9%)
They could be discussed with a public health nurse	8 (38.1%)
They could be discussed with a nurse practitioner	7 (33.3%)
There were shown in a support group followed by discussion	6 (28.6%)
They could be used with additional resources	5 (23.8%)
The women could call a 1-800 number for more info	2 (9.5%)
Used on their own	2 (9.5%)
Other	1 (4.8%)

Was there any part of this video that you particularly liked (e.g. patient testimonies, diagrams)?

- Patient testimonies (6)
- Diagrams (6)
- Doctors' explanations (1)
- Details about medical treatments (1)
- Description of treatment options (1)
- The doctor who was the main speaker who tied everything together (1)
- All of the video provided information that was very educational (1)

How could this video be improved?

- Broaden age range (2)
- A more multicultural perspective, subtitles for ethnic groups (AUB is common in Chinese population) (1)
- By saying where it is available – sale or rent? (1)
- Information about indications, side effects, risks and results of research (1)
- Showing actual surgery (1)
- Take through a case scenario from occurrence to testing to decision-making (1)
- More depth (1)
- Too wordy (1)
- Just right (1)
- Very informative for lay people (1)
- Video was thorough (1)

I found the language in this video to be:

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- More depth (1)
- Too wordy (1)
- Just right (1)
- Very informative for lay people (1)
- Video was thorough (1)

Are there changes that should be made to make this video more relevant to Ontario women?

- No (4)
- Statistics from Ontario/Canada (2)
- Statistics in Ontario/ Toronto about surgery treatments and confidence level (1)
- The video was basic and general – important on both sides of the border (1)
- A multicultural perspective, a more diverse portrait of health care providers and participants (1)
- Availability of treatments/drugs in Canada/Ontario (1)
- Choice of women may be different in Canada. (1)
- Cost factors, where best care could be provided, waiting time for treatments, availability of specialists (1)
- Information about indications, side effects, risks and results of research (1)
- Length of stay post-op would be shorter in Ontario (1)
- Influence by family and doctor rather than making own decision (1)

Where would you like to access this type of information video?

	N (%)
Doctor's office	14 (66.7%)
Public library	12 (57.1%)
Community health centre	8 (38.1%)
Local pharmacy	8 (38.1%)
Public health unit	7 (33.3%)

Overall rating of this video:

	N (%)
1– Poor	0
2	0
3	1 (5%)
4	12 (60%)
5– Excellent	7 (35%)

Would you like to see videotapes like this one related to other women's health conditions?

	N (%)
Yes	1 (5%)
No	19 (95%)

What conditions would you like to see videotapes about?

- Breast cancer and breast exams (4)
- Heart disease (3)
- Osteoporosis (2)
- Cervical cancer (1)
- Depression (1)
- Digestive disorders (1)
- Thyroid problems (1)
- Gynecology (1)
- Menopause (1)
- Mitral valve and aortic valve regurgitation and heart problems (1)
- Diabetes (1)
- All, especially cancer (1)
- Hypertension (1)
- Ovarian cancer (1)
- General medical issues (1)
- Good educational tool for most diseases (1)

Age

Minimum	Maximum	Mean	Standard deviation
25	75	51.89	14.951

Why did you attend this session?

	N (%)
General interest	12 (57.1%)
I am a health educator/health professional	9 (42.9%)
I have health problems related to this video	5 (23.8%)
A family member or friend has health problems related to this video	4 (19%)
I am considering having a hysterectomy	1 (4.8%)
I have had a hysterectomy	0

Are there changes that should be made to make this video more relevant to Ontario women?

- No (4)
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- Gynecology (1)
- Menopause (1)
- Mitral valve and aortic valve regurgitation and heart problems (1)
- Diabetes (1)
- All, especially cancer (1)
- Hypertension (1)
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APPENDIX G – PROVINCIAL DISTRIBUTION OF GENERAL PRACTITIONERS, FAMILY PHYSICIANS & OBSTETRICIANS/GYNAECOLOGISTS

GENERAL PRACTITIONERS (GPS) AND FAMILY PHYSICIANS (FPS), ONTARIO AND REGIONS, 2000

Region	No. of Active GP/FPs	Population	GP/FPs per 100,000 pop	% +/- prov. avg.
Southwest	1,088	1,519,930	71.58	-15%
Central West	1,482	2,072,478	71.51	-15%
Central South	828	1,158,170	71.49	-15%
Central East	1,350	1,919,582	70.33	-16%
Toronto	2,730	2,542,844	107.36	27%
East	1,575	1,569,146	100.37	19%
North	775	887,194	87.35	4%
Ontario	**9,828**	**11,669,344**	**84.22**	**0%**

OBSTETRICIANS/GYNAECOLOGISTS (OB/GYNS), ONTARIO AND REGIONS, 2000

Region	No. of Active Ob/Gyns	Population	Ob/Gyns per 100,000 pop	% +/- prov. avg.
Southwest	73	1,519,930	4.80	-8%
Central West	72	2,072,478	3.47	-34%
Central South	56	1,158,170	4.84	-8%
Central East	63	1,919,582	3.28	-37%
Toronto	212	2,542,844	8.34	59%
East	110	1,569,146	7.01	34%
North	24	887,194	2.71	-48%
Ontario	**610**	**11,669,344**	**5.23**	**0%**

Source: *Ontario Physician Human Resources Data Centre, Physicians in Ontario, 2000*
Ministry of Finance – Stats Canada Intercensal Estimates

APPENDIX G – PROVINCIAL DISTRIBUTION OF GENERAL PRACTITIONERS, FAMILY PHYSICIANS & OBSTETRICIANS/GYNAECOLOGISTS

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Ministry of Finance – Stats Canada Intercensal Estimates

Appendix H – Clinical Practice Guidelines

SOCIETY OF OBSTETRICIANS & GYNAECOLOGISTS CLINICAL PRACTICE GUIDELINES

Guidelines for the Management of Abnormal Uterine Bleeding (August 2001)

(Reprinted with permission.)

SOCIETY OF OBSTETRICIANS & GYNAECOLOGISTS CLINICAL PRACTICE GUIDELINES

Clinical Practice Guidelines for Hysterectomy (January 2002)

(Reprinted with permission.)

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS EVIDENCE-BASED CLINICAL GUIDELINE NO. 1

The Initial Management of Menorrhagia (February 1998)

(Reprinted with permission)

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS EVIDENCE-BASED CLINICAL GUIDELINE NO. 5

The Management of Menorrhagia in Secondary Care (July 1999)

(Reprinted with permission)

SOGC CLINICAL PRACTICE GUIDELINES

No. 106, August 2001

GUIDELINES FOR THE MANAGEMENT OF ABNORMAL UTERINE BLEEDING

These guidelines have been reviewed by the Clinical Practice Gynaecology and the Reproductive Endocrinology Infertility Committees, and approved by Executive and Council of the Society of Obstetricians and Gynaecologists of Canada

PRINCIPAL AUTHORS

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Abstract

Objective: It is estimated that nine to 30 percent of reproductive age women suffer from menorrhagia. The prevalence increases with age, peaking just prior to menopause. Menorrhagia and uterine fibroids account for up to 75 percent of all hysterectomies performed worldwide. This guideline provides recommendations to gynaecologists and other health care providers in the diagnosis and management of abnormal uterine bleeding, incorporating the current evidence.

Options: Diagnostic tools and medical and surgical alternatives to management are reviewed and current evidence is presented.

Evidence: Medline, Embase, and the Cochrane database were reviewed as well as other society guidelines.

Recommendations:

1. Women with irregular menstrual bleeding should be investigated for endometrial polyps and/or submucous fibroids. (II-2 B)
2. Women presenting with menorrhagia should have a current cervical cytology and a complete blood count. Further investigations are individualized. It is useful to delineate if the bleeding results from ovulatory or anovulatory causes, both in terms of tailoring the investigations and in choosing a treatment. (III B)
3. Clinicians should perform endometrial sampling based on the methods available to them. An office endometrial biopsy should be obtained if possible in all women presenting with abnormal uterine bleeding, over 40 years of age or weighing more than or equal to 90 kg. (II B)
4. Hysteroscopically-directed biopsy is indicated for women with persistent erratic menstrual bleeding, failed medical therapy or transvaginal saline sonography suggestive of focal intrauterine pathology such as polyps or myomas. Women with persistent symptoms but negative tests should be reevaluated. (II B)
5. Progestogens given in the luteal phase of the ovulatory menstrual cycles are not effective in reducing regular heavy menstrual bleeding. (I A)
6. While dilatation and curettage (D&C) may have a diagnostic role, it is not effective therapy for women with heavy menstrual bleeding. (II B)
7. The endometrium can be destroyed by several different techniques but reoperation rate at five years may be up to 40 percent with rollerball ablation. This should be reserved for the woman who has finished her childbearing and is aware of the risk of recurrent bleeding. (I A)

Sponsors: This guideline was produced by the Society of Obstetricians and Gynaecologists of Canada.

INTRODUCTION

The normal menstrual cycle lasts 28 ± 7 days, the flow lasts 4 ± 2 days, and the average blood loss is 40 ± 20 ml.[1]

Abnormal uterine bleeding (AUB) is defined as changes in frequency of menses, duration of flow or amount of blood loss. Dysfunctional uterine bleeding (DUB) is a diagnosis of exclusion when there is no pelvic pathology or underlying medical cause. DUB is typically characterized by heavy prolonged flow with or without breakthrough bleeding. It may occur with or without ovulation.

These guidelines reflect emerging clinical and scientific advances as of the date issued and are subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of the contents may be reproduced in any form without prior written permission of SOGC.

FOR INFORMATION ON THE SELF-DIRECTED LEARNING EXERCISE SEE PAGE 742

Menorrhagia (hypermenorrhoea) is defined as heavy cyclical menstrual bleeding occurring over several consecutive cycles during the reproductive years. Objectively menorrhagia is defined as blood loss of more than 80 ml per cycle, the 90th percentile in a study of 476 Gothenberg women published by Hallberg *et al.* in 1966.[2] Monthly blood loss in excess of 60 ml may result in iron deficiency anemia and may affect the quality of life.[3]

DIAGNOSTIC APPROACH TO AUB

HISTORY

It is important to distinguish anovulatory AUB, which is more likely to lead to endometrial hyperplasia, from ovulatory AUB. Women presenting with ovulatory AUB will likely have heavy cyclical menstrual blood loss over several consecutive cycles without any intermenstrual or postcoital bleeding. They may have dysmenorrhea associated with passing of clots. Premenstrual symptoms also suggest ovulatory cycles. The history should include symptoms suggestive of other pathology, such as irregular bleeding, postcoital bleeding, and pelvic pain. Polyps or submucous fibroids are present in 25 to 50 percent of women who present with irregular bleeding.[4,5]

DIAGNOSIS

A thorough abdominal and pelvic examination is essential. Cervical cytology should be obtained if indicated. A complete blood count (CBC ± ferritin) is needed to determine degree of anemia. Other investigations to be considered include: thyrotropin stimulating hormone, when other symptoms of thyroid dysfunction are present; prolactin; day 21 to 23 progesterone to verify ovulatory status; follicular stimulating hormone and luteinizing hormone to verify menopausal status or support a diagnosis of polycystic ovarian disease; and a coagulation profile when menorrhagia is present at puberty or if there is a clinical suspicion for a coagulopathy.

ASSESSMENT OF THE ENDOMETRIUM

Endometrial assessment is performed to diagnose malignancy or pre-malignant conditions and to evaluate the hormonal influences of the endometrium. Spencer *et al.* reviewed 142 studies to determine the value of endometrial evaluation methods in women with AUB. The data does not support a uniform recommendation for endometrial evaluation.[6]

Sampling of the endometrium should be considered in all women over 40 years of age with abnormal bleeding or in women who are at higher risk of endometrial cancer,[1,7] including: nulliparity with a history of infertility; new onset of heavy, irregular bleeding; obesity (≥ 90 kg);[7,8] polycystic ovaries;[9] a family history of endometrial and colonic cancer;[7] and on tamoxifen therapy.[10,11]

It is also important to evaluate the endometrial histopathology in a woman who has no improvement in her bleeding pattern following a course of therapy of three months. The SOGC guidelines *Diagnosis of Endometrial Cancer in Women With Abnormal Vaginal Bleeding* (2000) reviewed the evidence for endometrial sampling and contained an algorithm which suggests a course of management in assessing the endometrium.[12]

TECHNIQUES FOR ENDOMETRIAL SAMPLING

Office endometrial biopsy results in adequate samples 87 to 97 percent of the time[13,15] and detects 67 to 96 percent of endometrial carcinomas.[13,15] Although the choice of sampling device may affect accuracy, no existing method will sample the entire endometrium.[6] Hysteroscopically-directed sampling detects a higher percentage of abnormalities when compared directly with dilatation and curettage (D&C) as a diagnostic procedure.[16-18] Even if the uterine cavity appears normal at hysteroscopy, the endometrium should be sampled since hysteroscopy alone is not sufficient to exclude endometrial neoplasia and carcinoma.[19,20] (II A)

DILATATION AND CURETTAGE

In 10 to 25 percent of women D&C alone does not uncover endometrial pathology.[21] D&C was associated with uterine perforation in 0.6 to 1.3 percent of cases and hemorrhage in 0.4 percent of cases.[21] D&C is a blind procedure with significant sampling errors; it also requires anesthesia which carries a risk of complications. It should be reserved for those situations

TABLE I

INDEPENDENT RISK FACTORS FOR ENDOMETRIAL HYPERPLASIA AND CARCINOMA IN WOMEN WITH AUB[7,13]

Factor	Prevalence	Odds ratio and 95% CI	p value
All patients	4.9%	—	—
Weight ≥ 90 kg	12.7%	5.5 (2.9-10.6)	< 0.0001
Age ≥ 45 yr	7.9%	3.1 (1.5-6.1)	0.0016
Weight ≥ 90 kg and age ≥ 45 yr	22.2%	—	—
Weight ≥ 90 kg and age < 45 yr	2.3%	—	—
Family history of colon cancer	—	5.0 (1.3-19.1)	0.0182
Infertility	—	3.6 (1.3-9.9)	0.0127
Nulliparity	—	2.8 (1.1-7.2)	0.0267
Family history of endometrial cancer	—	5.8 (1.1-28.6)	0.0392

Farquhar *et al.*, 1999.[7] Multivariate analysis of 1033 women.

where office biopsy or directed hysteroscopic biopsy are not available or feasible.[21,22] (II B)

ULTRASOUND EXAMINATION OF THE ENDOMETRIUM

Transvaginal sonography (TVS) assesses endometrial thickness and detects polyps and myomata with a sensitivity of 80 percent and specificity of 69 percent.[23]

Although there is evidence that endometrial thickness may be indicative of pathology in the postmenopausal woman, such evidence is lacking for the woman in her reproductive years. Meta-analysis of 35 studies showed that in menopausal women, endometrial thickness of five mm at ultrasound has a sensitivity of 92 percent for detecting endometrial disease and 96 percent for detecting cancer.[24] It is not helpful when the thickness is between five and 12 mm.[25] No such correlations are firmly established in the premenopausal patient.[5,12,23,26]

SALINE SONOHYSTEROGRAPHY

The introduction of five to 15 mL of saline into the uterine cavity using a saline primed catheter or a pediatric feeding tube may improve the diagnosis of intrauterine masses during TVS.[6,27-30]

TREATMENT OF AUB

MEDICAL MANAGEMENT

Age, desire to preserve fertility, coexisting medical conditions, and patient preference are essential considerations. For each of the suggested methods, the patient should be aware of the risks and contraindications to allow informed choice. The degree of patient satisfaction may be influenced by efficacy, expectations, cost, inconvenience, and side effects.

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

Endometrial prostaglandins are elevated in women with heavy menstrual bleeding.[31,32] Non-steroidal anti-inflammatory drugs (NSAIDs) inhibit cyclo-oxygenase[31,32] and reduce endometrial prostaglandin levels.[31] In a review of 21 randomized controlled trials, NSAIDs taken with menses decrease menstrual blood loss by 20 to 50 percent.[33,34] NSAIDs improve dysmenorrhea in up to 70 percent of patients.[33] Therapy should start at the first day of menses and be continued for five days or until cessation of menstruation. (I A)

ANTIFIBRINOLYTIC AGENTS

Tranexamic acid (cyclokapron), a synthetic derivative of the amino acid lysine, exerts an antifibrinolytic effect through reversible blockade on plasminogen.[35,36] The drug has no effect on blood coagulation parameters or dysmenorrhea.[35,36] One-third of women experience side effects, including nausea and leg cramps. Tranexamic acid one g every six hours for the first four days of the cycle reduces menstrual blood loss by up to 40 percent, based on 10 randomized placebo-controlled trials.[33,35,36] (I A)

DANAZOL

Danazol, a synthetic steroid with mild androgenic properties, inhibits steroidogenesis in the ovary and has a profound effect on endometrial tissue,[37] reducing menstrual blood loss by up to 80 percent.[38-41] Following danazol therapy (100-200 mg daily), 20 percent of patients reported amenorrhea and 70 percent reported oligomenorrhea. Approximately 50 percent of the patients reported no side effects with danazol while 20 percent reported minor but acceptable side effects.[38,39] The most common complaint was weight gain of two to six pounds in 60 percent of patients. The recommended treatment is 100 to 200 mg daily for three months.[39,40]

PROGESTINS

Randomized controlled trials have shown cyclic progestins to be ineffective in controlling regular heavy menstrual bleeding compared to NSAIDs and tranexamic acid.[42-44] Progestins may be useful for women with irregular cycles and with anovulatory cycles when given for 12 to 14 days of each month.[45] Medroxyprogesterone acetate given for contraception induces amenorrhea within the first year in 80 percent of women,[46] although as many as 50 percent experience irregular bleeding.[46]

COMBINED ORAL CONTRACEPTIVE PILL

The reduction of menstrual blood loss with the combined oral contraceptive pill (OC) is probably the result of induced endometrial atrophy. A randomized controlled trial of women taking an OC containing 30 µg ethinyl estradiol showed a 43 percent reduction in menstrual blood loss compared to baseline.[47] Two longitudinal case control studies have found that users were less likely to experience heavy menstrual bleeding or anemia.[48] Additional advantages of OCs include contraception and reduction of dysmenorrhea.

PROGESTIN INTRAUTERINE SYSTEM

Progesterone impregnated intrauterine devices (IUDs) have been reported to reduce menstrual bleeding.[49-52] The newest levonorgestrel intrauterine system (LNG-IUS) is a T-shaped IUD which releases a steady amount of levonorgestrel (20 µg/24 hrs) from a steroid reservoir around the vertical stems of the device. It is presently undergoing clinical investigation in Canada and is expected to be released within the next few months.

GnRH AGONISTS

GnRH agonists induce a reversible hypoestrogenic state, reducing total uterine volume by 40 to 60 percent.[53] Myomas and uterine volume expand to pretreatment levels within months of cessation of therapy.[53] GnRH agonists are effective in reducing menstrual blood loss in perimenopausal women, but are limited by their side effects, including hot flashes and reduction of bone density.[53]

SURGICAL MANAGEMENT

DILATATION AND CURETTAGE

There are no published reports of randomized controlled trials comparing D&C and other potential treatments for the relief of menorrhagia.[22] The only study to measure blood loss before and after D&C found temporary reduction in menstrual blood loss immediately after the procedure; however, losses returned to previous levels or higher by the second menstrual period post-intervention.[22,54] D&C may have a diagnostic role when endometrial biopsy is inconclusive and the symptoms persist or when underlying pathology is suspected.[12]

ENDOMETRIAL DESTRUCTION

Endometrial destruction can be performed by several surgical techniques. Hysteroscopic endometrial ablation with photocoagulation, rollerball, electrocoagulation or loop resection, and their long-term results, have been reviewed by Martyn.[55] Endometrial ablation has now been evaluated clinically for the past 20 years. Several studies with life table analysis up to 6.5 years have shown satisfaction rates of approximately 85 percent.[55] Within the study periods, approximately 10 percent of women will move on to hysterectomy and 10 percent will require a repeat endometrial ablation for failed initial treatment.[55] Patients undergoing surgery after age 40 years appear to have a better outcome.[55] There is no clear evidence that the presence of fibroids or dysmenorrhea prior to endometrial ablation surgery reduces the rates of success. Preoperative medical treatment does not appear to improve long-term outcome but does improve ease of surgery and short-term amenorrhea rates.[55] Hysteroscopic endometrial ablation is an effective treatment for the management of chronic menorrhagia unresponsive to medical therapy, with acceptably low complication rates and high patient satisfaction rates when assessed at long-term follow-up.[55] Reoperation rate at five years may be up to 40 percent with rollerball ablation.[55] Endometrial ablation compares favourably with hysterectomy in randomized trials comparing efficacy and cost,[56] although the long-term analysis should include the cost of further therapy in women who require additional procedures.

Global endometrial ablation, recently reviewed by Vilos, was introduced in the 1990s as an easier, safe, and equally effective alternative to hysteroscopic ablation.[57] Several different devices, some of which are still undergoing feasibility studies or clinical trials, have been introduced, including: hot water intrauterine balloons, intrauterine free saline solution, an electrocoagulating balloon, a 3-D bipolar electrocoagulation probe, a microwave device, a diode fibre laser, and several different cryoprobes.[57] These devices require less operator skill than for hysteroscopic endometrial ablation and no irrigant or distending solutions. All utilize either heat or cold to destroy the endometrium. Although all devices are promising and have produced impressive preliminary results, the long-term efficacy, complication rates, and cost effectiveness have not been established.

Since all procedures are performed without hysteroscopic visualization (except hydrothermablation), it would be prudent to perform hysteroscopy prior to and following the treatment to ensure that only the endometrial cavity has been treated. False passages and partial or complete uterine perforations occur at a frequency of 0.8 to 1.5 percent and may result in adjacent organ injury.[57]

HYSTERECTOMY

The risks of major surgery must be weighed against alternatives. Clinical practice guidelines for hysterectomy have been reported by Lefebvre *et al.*[58] Hysterectomy is a permanent solution for the treatment of menorrhagia and abnormal uterine bleeding, and is associated with high levels of patient satisfaction in properly selected patients. For the woman who has completed her childbearing, reviewed the alternatives, and has tried conservative therapy without acceptable results, hysterectomy is often the best choice.

RECOMMENDATIONS

1. Women with irregular menstrual bleeding should be investigated for endometrial polyps and/or submucous fibroids. (II-2 B)
2. Women presenting with menorrhagia should have a current cervical cytology and a complete blood count. Further investigations are individualized. It is useful to delineate if the bleeding results from ovulatory or anovulatory causes, both in terms of tailoring the investigations and in choosing a treatment. (III B)
3. Clinicians should perform endometrial sampling based on the methods available to them. An office endometrial biopsy should be obtained if possible in all women presenting with abnormal uterine bleeding over 40 years of age or weighing more than or equal to 90 kg. (II B)
4. Hysteroscopically-directed biopsy is indicated for women with persistent erratic menstrual bleeding, failed medical therapy or transvaginal saline sonography suggestive of focal intrauterine pathology such as polyps or myomas. Women with persistent symptoms but negative tests should be reevaluated. (II B)

TABLE 2

ADVANTAGES OF GLOBAL ENDOMETRIAL ABLATION[57]

1. Devices are relatively safe but the overall safety will not be determined until several hundred procedures are performed by each device.
2. Devices are easier to use than hysteroscopic endometrial ablation.
3. Since the endometrium is destroyed, it is imperative that endometrial neoplasia be excluded.

5. Progestogens given in the luteal phase of the ovulatory menstrual cycles are not effective in reducing regular heavy menstrual bleeding . (I A)
6. While dilatation and curettage (D&C) may have a diagnostic role, it is not effective therapy for women with heavy menstrual bleeding. (II B)
7. The endometrium can be destroyed by several different techniques but reoperation rate at five years may be up to 40 percent with rollerball ablation. This should be reserved for the woman who has finished her childbearing and is aware of the risk of recurrent bleeding. (I A)

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TABLE 3

QUALITY OF EVIDENCE ASSESSMENT[59]	CLASSIFICATION OF RECOMMENDATIONS[59]
The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.[59] I: Evidence obtained from at least one properly randomized controlled trial. II-1: Evidence from well-designed controlled trials without randomization. II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group. II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940) could also be included in this category. III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.	Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.[59] A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination. B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination. C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds. D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination. E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

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SOGC CLINICAL PRACTICE GUIDELINES

No. 109, January 2002

HYSTERECTOMY

The following Clinical Practice Guideline has been reviewed by the Clinical Practice Gynaecology Committee and approved by Executive Committee and Council of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: To identify the indications for hysterectomy, preoperative assessment, and available alternatives required prior to hysterectomy.

Patient self-reported outcomes of hysterectomy have revealed high levels of patient satisfaction. These may be maximized by careful preoperative assessment and discussion of other treatment choices. In most cases hysterectomy is performed to relieve symptoms and improve quality of life. The patient's preference regarding treatment alternatives must be considered carefully.

Options: The areas of clinical practice considered in formulating this guideline are preoperative assessment including alternative treatments, choice of method for hysterectomy, and evaluation of risks and benefits. The risk-to-benefit ratio must be examined individually by the woman and her health practitioners.

Outcomes: Optimizing the decision-making process of women and their caregivers in proceeding with a hysterectomy having considered the disease process, and available alternative treatments and options, and having reviewed the risks and anticipated benefits.

Evidence: Using Medline, PubMed, and the Cochrane Database, English language articles were reviewed from 1996 to 2001 as well as the review published in the 1996 SOGC guidelines. The level of evidence has been determined using the criteria described by the Canadian Task Force on the Periodic Health Examination.

Benefits, harms, and costs: Hysterectomy is the treatment of choice for certain gynaecologic conditions. The predicted advantages must be carefully weighed against the possible risks of the surgery and other treatment alternatives. In the properly selected patient, the result from the surgery should be an improvement in the quality of life. The cost of the surgery to the health care system and to the patient must be interpreted in the context of the cost of untreated conditions. The approach selected for the hysterectomy will impact on the cost of the surgery.

Recommendations:

Benign Disease

1. **Leiomyomas:** For symptomatic fibroids, hysterectomy provides a permanent solution to menorrhagia and the pressure symptoms related to an enlarged uterus. (I-A)
2. **Abnormal uterine bleeding:** Endometrial lesions must be excluded and medical alternatives should be considered as a first line of therapy. (III-B)
3. **Endometriosis:** Hysterectomy is often indicated in the presence of severe symptoms with failure of other treatments and when fertility is no longer desired. (I-B)
4. **Pelvic relaxation:** A surgical solution usually includes vaginal hysterectomy, but must include pelvic supporting procedures. (II-B)
5. **Pelvic pain:** A multidisciplinary approach is recommended, as there is little evidence that hysterectomy will cure chronic pelvic pain. When the pain is confined to dysmenorrhea or associated with significant pelvic disease, hysterectomy may offer relief. (II-C)

Preinvasive Disease

1. Hysterectomy is usually indicated for endometrial hyperplasia with atypia. (I-A)

These guidelines reflect emerging clinical and scientific advances as of the date issued and are subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of the contents may be reproduced in any form without prior written permission of SOGC.

2. Cervical intraepithelial neoplasia in itself is not an indication for hysterectomy. (I-B)
3. Simple hysterectomy is an option for treatment of adenocarcinoma *in situ* of the cervix when invasive disease has been excluded. (I-B)

Invasive Disease

1. Hysterectomy is an accepted treatment or staging procedure for endometrial carcinoma. It may play a role in the staging or treatment of cervical, epithelial ovarian, and fallopian tube carcinoma. (I-A)

Acute Conditions

1. Hysterectomy is indicated for intractable postpartum hemorrhage when conservative therapy has failed to control bleeding. (II-B)
2. Tubo-ovarian abscesses that are ruptured or do not respond to antibiotics may be treated with hysterectomy and bilateral salpingo-oophorectomy in selected cases. (I-C)
3. Hysterectomy may be required for cases of acute menorrhagia refractory to medical or conservative surgical treatment. (II-C)

Other Indications

1. Consultation with an oncologist or geneticist is recommended when considering hysterectomy and prophylactic oophorectomy for a familial history of ovarian cancer. (III-C)

Surgical Approach

1. The vaginal route should be considered as a first choice for all benign indications. The laparoscopic approach should be considered when it reduces the need for a laparotomy. (III-B)

Validation: Medline searches were performed in preparing this guideline with input from experts in their field across Canada. The guideline was reviewed and accepted by SOGC Council and Executive.

Sponsor: The Society of Obstetricians and Gynaecologists of Canada.

INTRODUCTION

Hysterectomy is the most frequently performed major surgical procedure in gynaecology.[1] In Health Canada statistics, between 1981 and 1997 the hysterectomy rate decreased from 937 to 628 per 100,000 women over age 35.[2] In 1998–99, 462 hysterectomies were performed per 100,000 women age 20 or older. The rate varies per region from a low of 434 in British Columbia to a high of 750 in Newfoundland. Within each province, the rate fluctuates significantly by region. No relationship has been established between these differences and patient outcomes or satisfaction.[2]

Hysterectomy has a wide range of indications which may not be amenable to confirmation by the pathologic examination of the specimen.[3,4] It is thus difficult to define objective markers for validation of indication. New technologies are emerging for conservative surgical management of abnormal uterine bleeding and fibroids, but there is a paucity of Level I evidence comparing these new technologies to the gold standard of hysterectomy, particularly in terms of long-term outcome and quality of life improvements.

In 1981–82, 22 percent of hysterectomies were performed vaginally. In 1999–2000, the proportion of vaginal hysterectomy had increased to 32 percent of all hysterectomies in Canada.[2] The average length of stay for abdominal hysterectomy decreased from 9.7 days in 1981–82 to 4.4 days in 1999–2000.[2] While choice of approach for the surgery is discussed in this document, ultimately it remains a decision for the individual surgeon in concert with his or her patient.

This guideline presents considerations involved in the decision-making process of choosing hysterectomy or alternative therapies for each of the more common indications. The decision to proceed to a hysterectomy rests with the woman who has been fully educated to the risks and expected benefits of this procedure. The quality of evidence reported in this guideline has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam (Table 1).[5]

INDICATIONS

BENIGN DISEASE

a) Abnormal Uterine Bleeding

Evaluation of a woman with abnormal uterine bleeding (AUB)[6] should rule out non-gynaecologic etiologies, reproductive tract problems such as cervical polyps, endometrial neoplasia and pregnancy-related causes. Hysteroscopy is particularly useful in the diagnosis of endometrial polyps and submucosal fibroids, which can easily be missed at the time of an office biopsy or curettage.[6]

One or more "medical" options should be presented to women with AUB prior to considering surgical treatment: these are reviewed in the SOGC guideline on the management of abnormal uterine bleeding.[6] Depending on the severity of the disease, the age of the patient, her cultural beliefs, and her desire to preserve fertility, an endometrial ablation or a hysterectomy can also be considered. Appendix A and B highlight the decision-making process.

The surgeon or gynaecologist who is prepared to perform a hysterectomy to treat AUB must be fully knowledgeable about all the medical alternatives and surgical management options and inform the patient of her choices of treatment. In patients where medical treatment or conservative surgery has failed to reduce and improve the bleeding, hysterectomy is associated with a high level of satisfaction.[7-11]

b) Uterine Leiomyomas

Uterine leiomyomas are the most common gynaecological tumour and are present in 30 percent of women of reproductive age.[12] Treatment must be individualized based on symptoms, the size and rate of growth of the uterus, and the patient's desire for fertility.

The indications for hysterectomy in a completely asymptomatic patient are few and include rapidly enlarging fibroids or enlarging fibroids after menopause when concerns of leiomyosarcoma are raised.[12]

A recent study shows no increase in perioperative complications in women with a uterus greater than 12-week size compared to women with a small uterus.[12] Hysterectomy need not be recommended as prophylaxis against increased operative morbidity associated with future growth.[12] In patients who have completed childbearing, hysterectomy is indicated as a permanent solution for leiomyomas causing substantial bleeding, anemia, or pelvic pressure.

When considering hysterectomy for menorrhagia presumed related to fibroids, other causes of menorrhagia should be ruled out. Endometrial sampling, when indicated, should be performed to exclude endometrial lesions. The possibility of a coagulopathy or thyroid dysfunction should be considered. Since leiomyomas rarely cause pain, other causes of pelvic pain should be excluded. Removing a fibroid uterus should not be expected to alleviate symptoms of incontinence.[13]

GnRH agonists have been shown to shrink fibroids to 50 percent of their initial volume, with the greatest effect apparent after 12 weeks of treatment. However, the use of GnRH agonists is limited due to their cost and hypoestrogenic side effects, including a decrease in bone mineral density. Treatment should be restricted to a three- to six-month interval, following which regrowth of fibroids is expected within 12 weeks.[14] The use of GnRH agonists along with estrogen replacement is still considered investigational. GnRH agonists may be given preoperatively to decrease the size of the fibroids, reduce symptoms, and increase the patient's hemoglobin preoperatively.[14]

The advantage of myomectomy is the preservation of the uterus. The desire for children is the most common indication for myomectomy instead of hysterectomy. Most patients presenting with infertility and associated uterine fibroids are found by additional investigations to have other causes for the infertility. A higher risk of blood loss and greater operative time can be expected with myomectomy than hysterectomy, although the risk of ureteric injury may be decreased with myomectomy. There is a 15 percent recurrence rate of fibroids, and 10 percent of women undergoing a myomectomy will eventually require a hysterectomy within 10 years.[15] In discussing the planned myomectomy, patients should be informed about the risk of eventually requiring a hysterectomy, dependent on intraoperative findings and course of surgery. In view of the increased morbidity of an abdominal approach for myomectomy, there are very limited indications for this operation.[15] Hysteroscopy has been proven effective for diagnosis and management of submucous fibroids. As with other approaches for myomectomy, there appears to be a 10 to 20 percent risk of requiring further intervention within five to 10 years of resection.[16]

Myolysis refers to the technique where an attempt is made to disrupt, diminish or abolish the blood supply to the fibroids in order to deprive them of nutrients, sex hormones, and growth factors, and cause shrinkage or complete degeneration of the myomas. Several techniques have been used since 1986, including the Nd:YAG laser and bipolar or monopolar electrosurgery. These procedures work best in the presence of fewer than three fibroids, where the largest fibroid measures less than 10 centimetres in diameter, and when the patient has been pretreated with a GnRH agonist for three months prior to surgery.[17] Treatment is more effective when performed with concomitant endometrial ablation, and is not recommended for women who wish to retain their fertility. At least three uterine ruptures in pregnancy following laparoscopic electromyolysis have been reported.[17]

TABLE I

QUALITY OF EVIDENCE ASSESSMENT[5]

The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

CLASSIFICATION OF RECOMMENDATIONS

Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.

A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.

B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.

C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.

D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.

E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

Uterine artery laparoscopic occlusion with clips or by transfemoral embolization to treat symptomatic fibroids was introduced during the last decade. Small series addressing the feasibility, complication rates, clinical outcome and patient satisfaction have been in general encouraging, although follow-up is limited. However, the durability of the treatment, the effect on hysterectomy rates, and the cost-benefit of the procedure and its impact on fertility and hormone homeostasis have not yet been established.[16]

c) Endometriosis

Medical treatment of endometriosis is frequently associated with metabolic and symptomatic side effects and has limited success in controlling symptoms due to adhesive disease or damaged pelvic organs.

Conservative surgery, with minimal disruption of the pelvic organs, may be relevant where fertility is a consideration, but has limited effect in long-term control of symptoms as indicated by cumulative recurrence rates of 13 percent at three years and 40 percent at five years.[18] There is Level I evidence that conservative ablative surgery is helpful for treatment of infertility in patients with minimal to mild endometriosis[19] and control of pelvic pain in patients with minimal to moderate endometriosis.[20]

The ultimate goal of treatment of endometriosis is the relief of symptoms, without incurring side effects. The decision to proceed to hysterectomy is a major step. This decision should be guided by three factors: 1) the presence of severe symptoms, particularly intractable pain, after other possible causes of pain have been treated or ruled out; 2) the failure of other treatments or intolerance to their side effects; 3) future pregnancy is no longer possible or desired.

Whether to preserve the ovaries when performing a hysterectomy for endometriosis is controversial. A large retrospective study compared recurrence of symptoms after hysterectomy with or without ovarian conservation with a mean follow-up of 58 months. In women with ovarian conservation, 62 percent had recurrent symptoms and 31 percent required further surgery, versus 10 percent and 3.7 percent in women who had had bilateral oophorectomies.[21] Several studies have found higher reoperation rates associated with more severe disease.[22-24] Women who have recurrent symptoms after hysterectomy and castration are likely to have persistent disease, most often involving the bowel.[25] In patients with severe disease who request definitive treatment for their symptoms, it is generally recommended that both ovaries and all visible endometriosis be removed, including bowel disease if symptomatic.[26] Bilateral oophorectomy cannot, however, be routinely recommended when performing a hysterectomy for earlier stage endometriosis after all visible lesions have been removed and the remaining ovarian tissue appears to be normal.

The effects of bilateral oophorectomy should be discussed preoperatively, along with the issue of symptom recurrence if ovaries are preserved, so that a surgical plan can be developed with the patient's input. If bilateral oophorectomy is performed, immediate hormonal replacement therapy should then be given in adequate dosage without fear of exacerbation of the disease.[21,24,26]

A thorough review of medical and surgical treatments can be found in the Canadian Consensus Conference on Endometriosis.[18,27]

d) Pelvic Relaxation

Symptoms attributable to prolapse include a sensation of protrusion, pelvic pressure, urinary incontinence, rectal discomfort, and discomfort related to the irritation of externalized mucosal tissues. Mild to moderate degrees of prolapse in the absence of complaints should rarely be corrected. The primary objectives of surgical treatment for symptomatic genital prolapse are the relief of symptoms, the reconstruction of pelvic supports, and the restoration of normal anatomy.[28] Removing the uterus is only part of any surgical procedure for pelvic relaxation. Concomitant correction of any cystocele or rectocele must be undertaken to restore support of the vagina. Attention to support of the vagina and obliteration of a potential enterocele will minimize the risks of post-hysterectomy vault prolapse.[29] Preoperative assessment should include careful physical examination to exclude intra-abdominal and pelvic lesions. The extent of the pelvic relaxation may then be evaluated. Urinary incontinence should be assessed.

Therapeutic alternatives may include estrogen replacement, pelvic floor exercises, and pessaries. The patient should be presented with options as alternatives, understanding the limitations of medical management. The long-term use of a vaginal pessary may be associated with vaginal erosion. Such patients should be monitored carefully with regular vaginal examinations.

There are no successful surgical alternatives to advanced uterine prolapse, other than hysterectomy and pelvic floor repair. Uterine suspension has been found generally ineffectual.[29] In patients with an isolated cystocele, coincidental hysterectomy for the removal of a non-prolapsing uterus is of uncertain benefit.[28]

e) Benign Adnexal Mass

A thorough examination of the medical literature reveals a lack of data addressing the use of incidental hysterectomy when removing a benign adnexal mass.

If a bilateral oophorectomy is indicated for a benign ovarian condition such as endometriosis, the possibility of hysterectomy should be discussed with the patient before the surgery and a management plan established. Whether there are any benefits of concomitant hysterectomy at the time of bilateral oophorectomy for conditions other than ovarian cancer, where no other indications exist, remains unknown. Options must be individualized.

The added surgical risks of hysterectomy in addition to the

removal of the adnexal mass include infection, ureteral trauma, and blood loss. The patient's desire for future fertility, previous menstrual history, and potential implications of hormone replacement therapy are other important factors to be considered and discussed with the patient.

f) Chronic Pelvic Pain

Pelvic pain should be carefully investigated prior to considering a hysterectomy. Investigations should include a careful gynaecologic examination, pelvic ultrasound, and evaluation of urinary, gastrointestinal, and musculoskeletal sources for pain as indicated by the presenting symptoms. A multidisciplinary approach should be undertaken. Psychiatric evaluation should be offered, as there is an association between psychosomatic factors and a history of sexual abuse.[30-32]

Medical management may include use of non-steroidal anti-inflammatory drugs, oral contraceptives, danazol, high-dose progestins or GnRH analogues. Laparoscopy should be considered to document and treat identifiable causes of pain. Any underlying cause should be addressed specifically. Treatment should be individualized. There is a case for hysterectomy when an underlying disease, amenable to hysterectomy, is demonstrated and the patient has completed her family. In the patient suffering exclusively from dysmenorrhea, hysterectomy may offer relief. There is little evidence to support the indications for hysterectomy in a patient with idiopathic pelvic pain and a high likelihood that the pain will persist following surgery.[33]

PRE-INVASIVE NEOPLASTIC DISEASES

a) Endometrial Hyperplasia

Endometrial hyperplasia is usually diagnosed because of a complaint of abnormal uterine bleeding which leads to either office endometrial sampling or a D & C. The most significant histological finding is the presence or absence of cytologic atypia.[34,35] The majority of patients without atypia will respond to hormonal manipulation in the form of progestin.[34,36] Endometrial hyperplasia with cytologic atypia on an endometrial biopsy warrants a hysteroscopy and D&C to rule out concomitant endometrial adenocarcinoma, which is present in 17 to 25 percent of cases.[37] Up to 25 percent of atypical endometrial hyperplasia may progress to endometrial cancer despite progestin therapy, with an average time of progression of four years.[34,36] For endometrial hyperplasia with atypia, either progestin therapy or simple hysterectomy are initial treatment options. When progestin therapy is chosen, patients should undergo a repeat endometrial sampling within six months. For patients with persistent endometrial hyperplasia or in patients who continue to experience irregular bleeding, a hysterectomy is recommended. Patients without atypia but with persistent hyperplasia on follow-up endometrial sampling despite a trial of both low and high dose progestin therapy may be treated by hysterectomy.[38]

b) Cervical Squamous Intraepithelial Neoplasia

Cervical squamous intraepithelial neoplasia (CIN) in itself is not an indication for hysterectomy. Hysterectomy is indicated only if there are other gynaecologic conditions that on their own justify the operation. However, it is important to exclude invasive cervical cancer prior to hysterectomy. Cervical squamous intraepithelial neoplasia should be treated by a conservative technique such as cryotherapy, laser, electrosurgical excision, or cone biopsy. Hysterectomy is indicated for failure of conservative therapy.[38]

c) Adenocarcinoma *in situ*

Adenocarcinoma *in situ* accounts for approximately two percent of *in situ* carcinomas of the cervix. Fifty percent of adenocarcinomas *in situ* will have an associated squamous lesion.[39-41] Prior to performing a hysterectomy, a cylindrical-shaped cone biopsy is necessary to rule out invasive adenocarcinoma.[42,43] For women who have completed their families, a simple hysterectomy is a treatment option. If the cone biopsy margin, however, is positive for *in situ* disease, a repeat cone biopsy is necessary to rule out invasive adenocarcinoma of the cervix.

INVASIVE DISEASE

a) Uterine Carcinoma

Endometrial cancer is the most common gynaecologic malignancy and it accounts for over 95 percent of uterine cancers, while uterine sarcomas are much less common.[38] Both endometrial cancer and uterine sarcomas are best treated by hysterectomy. In the case of sarcomas, hysterectomy is the only treatment that offers a chance of cure.

Laparotomy for endometrial cancer should include full surgical staging. If surgery is not possible, usually because the woman is medically unfit for surgery, alternative therapy includes pelvic radiotherapy and/or progestin treatment. Radiation therapy is less likely to be curative and progestin therapy is only palliative.[38]

b) Cervical Carcinoma

Cervical cancer can be treated equally well by either surgery or radiotherapy, the identical cure rate being 85 percent five year survival for stage 1 disease. Radiotherapy and concurrent chemotherapy is appropriate for more advanced stage disease.[44] Surgery is usually the option when the patient is in good physical condition; age in itself is not an exclusion criterion. Bladder and bowel injuries as a consequence of surgery are uncommon and without long-term sequelae.[45] Bowel and bladder injuries secondary to radiotherapy are more difficult to treat and also relatively uncommon.

Microinvasive squamous cell carcinoma of the cervix is classified as a depth of invasion less than 0.3 mm with no capillary or lymph vascular space involvement. A simple hysterectomy or cone biopsy is adequate treatment for microinvasive

disease, with patient choice usually dependent on the woman's desire for fertility preservation. More advanced lesions require radical hysterectomy and pelvic lymphadenectomy.[38] A definition of microinvasive adenocarcinoma of the cervix that precludes any significant risk of metastatic disease has not been reached.[46]

Conventional therapy for invasive adenocarcinoma of the cervix includes either modified radical hysterectomy plus bilateral pelvic lymphadenectomies or pelvic radiotherapy. Any other form of treatment must be individualized after appropriate consultation.

c) Epithelial Ovarian Cancer

Epithelial ovarian cancer usually presents in advanced stages. Fifty to 60 percent of women diagnosed with ovarian cancer and appropriately treated will die of this disease.[38] Although the treatment of advanced epithelial ovarian cancer includes hysterectomy, there is no data to show that this alters prognosis. After hysterectomy, a mass palpable at the vault will represent disease and may be used to evaluate response to adjuvant chemotherapy. In cases of advanced stage carcinoma, hysterectomy can facilitate debulking of disease from the pelvis. Concomitant hysterectomy is recommended by most oncologists.

The uterus and contralateral ovary may be retained to preserve fertility in a woman who has undergone a full surgical staging procedure and is found to have stage Ia, grade 1 or grade 2 disease. However, once her family is complete an oophorectomy should be performed and hysterectomy may be offered (see "Prophylaxis"). In non-epithelial ovarian cancers the need for hysterectomy should be individualized.

d) Germ Cell Tumours of the Ovary

Germ cell tumours tend to occur in young women and are usually unilateral. Surgery should include removal of the affected ovary and staging for ovarian cancer. A hysterectomy and contralateral oophorectomy is usually not indicated.

e) Fallopian Tube and Primary Peritoneal Papillary Serous Carcinoma

Hysterectomy is indicated in the case of fallopian tube cancer to ensure all of the fallopian tube has been removed and to ensure accurate follow-up. In primary peritoneal papillary serous carcinoma, total abdominal hysterectomy and bilateral salpingo-oophorectomy is necessary to exclude a primary malignancy in the endometrium, fallopian tube, or ovaries.

ACUTE CONDITIONS

a) Pregnancy Related Hemorrhage

Emergency peripartum hysterectomy is generally performed in the setting of life-threatening hemorrhage. The incidence of emergency hysterectomy is 1.55 per 1,000 deliveries.[47,48] This procedure is performed more often after Caesarean section (0.7%) than vaginal delivery (0.02%).[48] In one study, abnormal placentation was the most common cause (64%) followed by uterine atony (21%). Other etiologies included uterine rupture, fibroids, and extension of a uterine scar.[47]

When intractable obstetric hemorrhage is caused by any of these conditions, immediate and deliberate action is mandatory and may be lifesaving. However, it must be emphasized that conservative measures to control obstetric hemorrhage remain the mainstay of therapy. In the management of hemorrhage caused by uterine atony, a medical stepwise approach is recommended.[49] The obstetrician must assure that the products of conception are totally removed.

Different therapeutic agents such as oxytocin, methylergonovine-maleate, and PGF 2-alpha must be used to control hemorrhage. Surgery is reserved for cases refractory to non-surgical treatment. Embolization of uterine arteries can be used in the stable patient. Ligation of hypogastric or uterine arteries may be attempted to control hemorrhage prior to resorting to a hysterectomy.[29,50,51]

Hysterectomy for the control of obstetric hemorrhage is clearly a procedure associated with significant morbidity and mortality.[47,48]

When required, the obstetrician should usually plan to perform a total hysterectomy. In some circumstances, subtotal hysterectomy may be the procedure of choice if the medical condition of the patient is unstable.

b) Severe Infection

With the development of broad-spectrum antibiotics, the management of tubo-ovarian abscess (TOA) has changed from total abdominal hysterectomy and bilateral salpingo-oophorectomy to a medical approach. Now there are three main indications for surgical intervention in patients with a suspected TOA: intra-abdominal rupture of TOA, suspicion of other surgical emergencies (such as appendicitis), and failure to respond to appropriate antibiotic therapy within 48 to 72 hours.[52]

Rupture of TOA is a life-threatening condition requiring urgent surgical management. Generalized peritonitis may occur. Death is usually due to the resulting sepsis. The traditional approach has been a complete hysterectomy with bilateral salpingo-oophorectomy. Even with the help of antibiotics, it seems that complete gynaecologic extirpation is the treatment of choice when there is extensive bilateral involvement. However, when unilateral disease is demonstrated, broad-spectrum intravenous antibiotic therapy with unilateral adnexectomy appears to be a safe alternative in patients who desire to preserve reproductive capability and ovarian hormone production.[53,54]

The surgical management of unruptured TOA is less clear. Surgical drainage can be done by laparotomy, posterior colpotomy, operative laparoscopy[55,56] or with interventional radiologic technique.[52] The clinical situation will guide the physician for the choice of the best surgical approach. Total abdominal

hysterectomy with bilateral salpingo-oophorectomy is an option that may be considered by the surgeon.[55]

OTHER INDICATIONS

a) Prophylaxis

The term "prophylactic hysterectomy" describes hysterectomy performed at the time of other surgery for benign pelvic disease. Infectious morbidity will almost certainly be increased as the result of entering the vagina. The medical literature has not quantified the level of the increased morbidity. Vaginal cuff cellulitis and wound infection are specifically likely to be increased.

The justification for a prophylactic hysterectomy may be related to hormone replacement therapy and the benefit of estrogen "alone" versus estrogen combined with progestin. Certainly endometrial cancer will no longer be a concern and withdrawal bleeding and other side effects of progestin will not be a factor. The use of hysterectomy in such situations should be individualized, discussed with the patient prior to surgery, and consent for options achieved.

b) Familial Ovarian Cancer

This group of patients may be subdivided into those with site-specific familial ovarian cancer, breast/ovarian familial cancer syndrome, and Lynch II syndrome which is now referred to as hereditary non-polyposis colon cancer (HNPCC). When preventive or prophylactic oophorectomy is planned, a concomitant hysterectomy should be considered.[57] Women at high risk of developing epithelial ovarian cancer because they carry BRCA1 or BRCA2 mutations are also at high risk for fallopian tube carcinoma and papillary serous carcinoma of the uterus.[58] In HNPCC Syndrome, depending on the family history, there may be a sufficiently increased risk of endometrial cancer to justify prophylactic hysterectomy as opposed to endometrial monitoring with ultrasound or endometrial biopsies.

c) Extenuating Circumstances

These guidelines have attempted to cover all areas of indications for hysterectomy. It should be realized that all possible indications may not have been covered. There may also be situations not supported by these guidelines. In such circumstances the gynaecologist should consider alternative approaches, and if hysterectomy is still felt to be the best option it may be prudent to have the reasons well documented and to obtain a second opinion of a colleague gynaecologist.

APPROACH FOR HYSTERECTOMY

The approach for hysterectomy depends on the surgeon's expertise, the indication for surgery, the nature of the disease, patient characteristics, and patient choice. Each case must be individualized. Options include vaginal hysterectomy, laparoscopic assisted vaginal hysterectomy (LAVH), laparoscopic supracervical hysterectomy (LSH), total laparoscopic hysterectomy (TLH), and abdominal hysterectomy (subtotal, total or radical).

Any patient requiring a hysterectomy should be offered the vaginal approach if feasible, as the post-operative rates of morbidity and complications are lower with the vaginal approach than with any other method. Appropriate prophylactic use of antibiotics is recommended to minimize febrile morbidity.

Subtotal hysterectomies were common from 1900 to 1940 as they were judged easier to perform with decreased morbidity and blood loss than when the cervix was removed. The operation fell into disfavour with improvement in surgical technique and anesthesia but is now attracting renewed attention. The prevention of cervical cancer remains the major reason not to do a subtotal hysterectomy. When a hysterectomy is performed for benign disease, subtotal surgery may be preferable to a patient who has always had normal cytological findings and who believes sexual function may be affected by removal of the cervix. There is no evidence that a subtotal hysterectomy reduces the risk of pelvic floor prolapse. As well, there is no evidence that a total hysterectomy will affect sexual function.[59]

LAVH may be chosen instead of an abdominal hysterectomy, but offers no advantage where a vaginal hysterectomy can be performed.[60,61] Prospective randomized trials comparing LAVH to the abdominal approach have found quicker recovery and less post-operative pain in the laparoscopic group.[62-64] The overall complication rate seems to be similar in both groups. In a Canadian setting, the laparoscopic route is associated with lower overall costs.[65] In many institutions, LSH is being performed with claims of shorter operating times, lower morbidity, and shorter convalescence.[66] There is no good prospective evidence that LSH has any advantages over LAVH. The same issues surrounding subtotal abdominal hysterectomy apply to LSH.

The laparoscopic approach does introduce new categories of complications in addition to the potential known complications shared with abdominal and vaginal hysterectomy. Trocar complications have been reported, most commonly abdominal wall vessel injury and intestinal herniation through large trocar sites. Inadvertent cystotomies with laparoscopic dissection and ureteral injuries with stapling devices have been reported more often, though their incidence is unknown. Nevertheless, in well selected cases laparoscopic hysterectomy can be a safe procedure with clear advantages to the patient if an abdominal procedure is avoided, as long as it is performed by a properly trained and skilled surgeon.

COMPLICATIONS OF HYSTERECTOMY

Rates of complications associated with hysterectomy range from 0.5 percent to 43 percent.[4] Post-operative fever and infection are responsible for the majority of minor complications. Routinely collected administrative data is of limited utility for determining the frequency of complications.[67] The reported incidence of

complications varies widely. In the four meta-analyses of laparoscopic hysterectomy series published between 1989 and 1995, the major complication rate was three to four percent, the total complication rate was 11.6 to 15.6 percent, and the mortality rate was zero to six per 100,000 cases. Major complications were defined as injuries to other organs or reoperations.[68]

A large analysis of over 160,000 hysterectomies in Ohio reported a complication rate of 9.1 percent for abdominal, 7.8 percent for vaginal, and 8.8 percent for laparoscopic approach to the hysterectomy.[69] Vesical and ureteric injuries are the most common source of major complications as compiled by the Finnish registry.[68] In a series of 13,885 hysterectomies,[68] the incidence of urinary tract injuries is highest with the laparoscopic approach (2.2%) and lowest with the vaginal hysterectomy (0.04%). When considering a hysterectomy, the patient should be informed of the risk of hemorrhage, infection, and damage to surrounding organs. There is no evidence that a hysterectomy leads to psychological distress.[7,70] Sexual function is unchanged or improved in 80 percent of patients following the operation.[59] Women suffering from depression prior to their hysterectomy are at greater risk for experiencing dyspareunia, vaginal dryness, and low libido after the hysterectomy.[70,71] Knowing what aspects may and may not be alleviated by hysterectomy for a particular condition can assist in decision-making and improve patient satisfaction.[11,70]

RECOMMENDATIONS

BENIGN DISEASE

1. **Leiomyomas:** For symptomatic fibroids, hysterectomy provides a permanent solution to menorrhagia and the pressure symptoms related to an enlarged uterus. (I-A)

2. **Abnormal uterine bleeding:** Endometrial lesions must be excluded and medical alternatives should be considered as a first line of therapy. (III-B)

3. **Endometriosis:** Hysterectomy is often indicated in the presence of severe symptoms with failure of other treatments and when fertility is no longer desired. (I-B)

4. **Pelvic relaxation:** A surgical solution usually includes vaginal hysterectomy, but must include pelvic supporting procedures. (II-B)

5. **Pelvic pain:** A multidisciplinary approach is recommended, as there is little evidence that hysterectomy will cure chronic pelvic pain. When the pain is confined to dysmenorrhea or associated with significant pelvic disease, hysterectomy may offer relief. (II-C)

PREINVASIVE DISEASE

1. Hysterectomy is usually indicated for endometrial hyperplasia with atypia. (I-A)
2. Cervical intraepithelial neoplasia in itself is not an indication for hysterectomy. (I-B)
3. Simple hysterectomy is an option for treatment of adenocarcinoma *in situ* of the cervix when invasive disease has been excluded. (I-B)

INVASIVE DISEASE

1. Hysterectomy is an accepted treatment or staging procedure for endometrial carcinoma. It may play a role in the staging or treatment of cervical, epithelial ovarian, and fallopian tube carcinoma. (I-A)

ACUTE CONDITIONS

1. Hysterectomy is indicated for intractable postpartum hemorrhage when conservative therapy has failed to control bleeding. (II-B)
2. Tubo-ovarian abscesses which are ruptured or which do not respond to antibiotics may be treated with hysterectomy and bilateral salpingo-oophorectomy in selected cases. (I-C)
3. Hysterectomy may be required for cases of acute menorrhagia refractory to medical or conservative surgical treatment. (II-C)

OTHER INDICATIONS

1. Consultation with an oncologist or geneticist is recommended when considering hysterectomy and prophylactic oophorectomy for a familial history of ovarian cancer. (III-C)

SURGICAL APPROACH

1. The vaginal route should be considered as a first choice for all benign indications. The laparoscopic approach should be considered when it reduces the need for a laparotomy. (III-B)

CONCLUSIONS

Important outcomes for patients include relief of symptoms, minimal complications, and optimal quality of life. Hysterectomy is highly effective for relief of symptoms and improvement of quality of life.[7,68,69] In order to achieve the most favourable outcome, the appropriateness of the surgery must be carefully evaluated along with all available options in the context of the disease process. The patient's preference regarding therapeutic strategy is of major importance.

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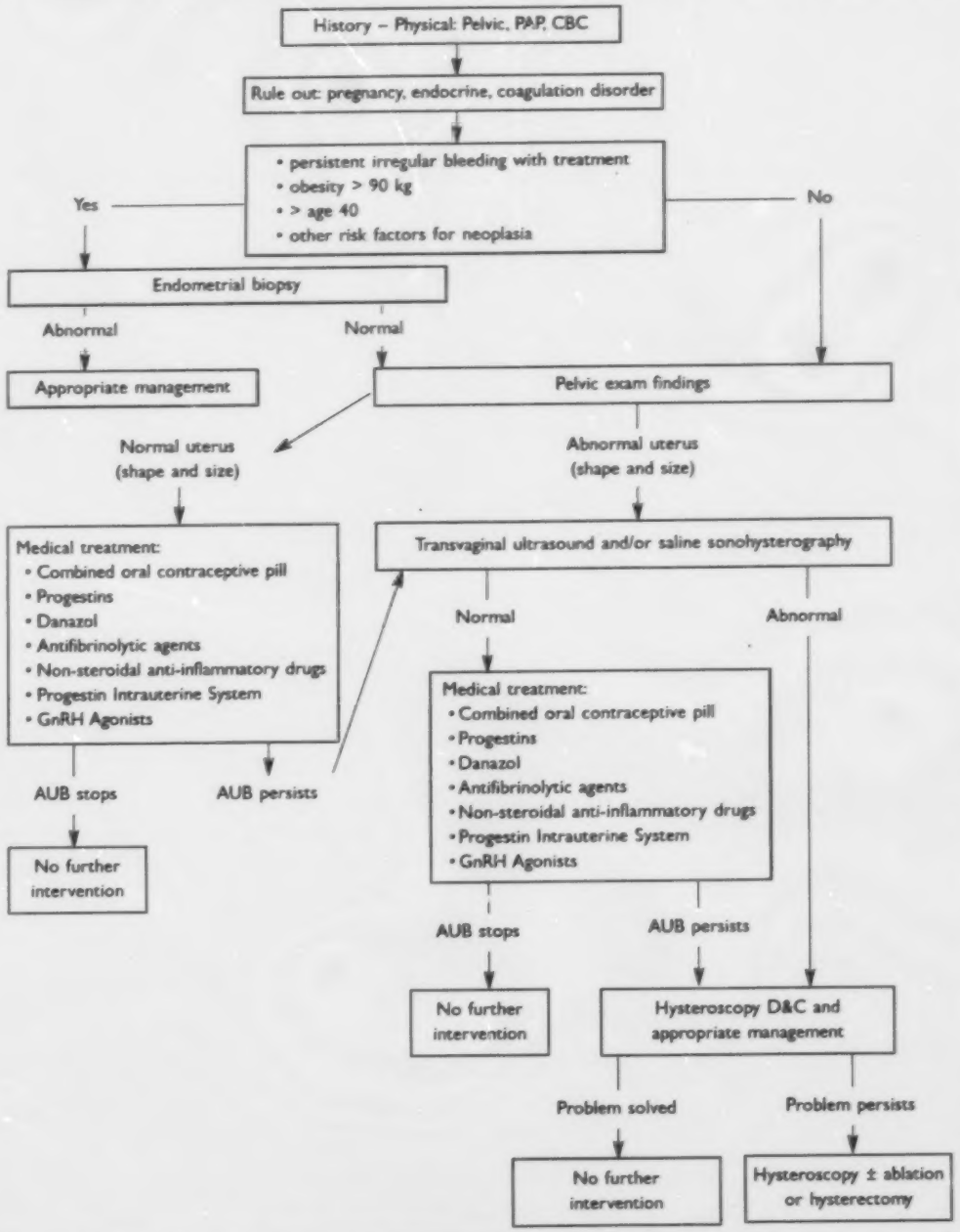
APPENDIX A

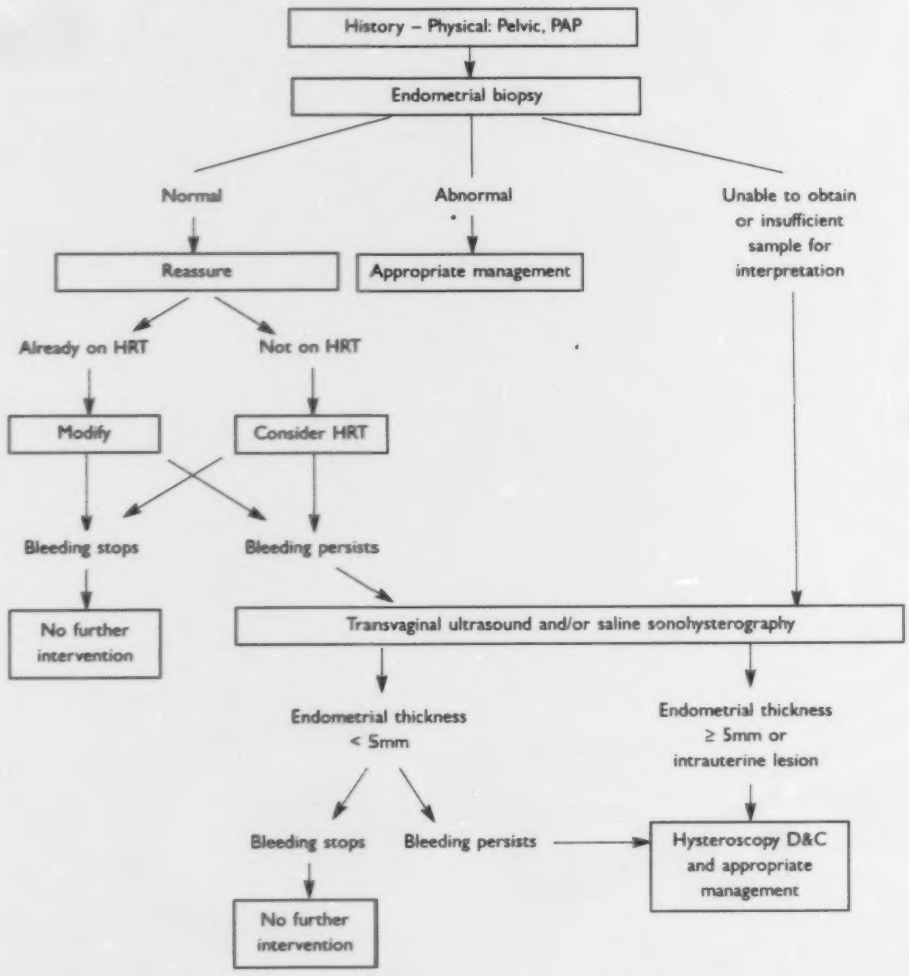
MANAGEMENT OF ABNORMAL UTERINE BLEEDING: PRE-MENOPAUSE

Abnormal uterine bleeding is defined as changes in frequency of menses, duration of flow or amount of blood loss. The normal menstrual cycle lasts 28 ± 7 days, the flow lasts 4 ± 2 days, and the average blood loss is of 40 ± 20 ml.



APPENDIX B

MANAGEMENT OF ABNORMAL UTERINE BLEEDING: POST-MENOPAUSE



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ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS EVIDENCE-BASED CLINICAL GUIDELINE NO. 1

THE INITIAL MANAGEMENT OF MENORRHAGIA

INTRODUCTION

Menorrhagia has an impact on many women's lives. One in 20 women aged 30-49 years consults her GP each year with menorrhagia. Once referred to a Gynaecologist, surgical intervention is highly likely. One in five women in the UK will have a hysterectomy before the age of 60 years. In at least half of those who undergo hysterectomies, menorrhagia is the main presenting problem. About half of all women who have a hysterectomy for menorrhagia have a normal uterus removed.

There are wide variations in the drugs prescribed in general practice for the management of menorrhagia, in the referral patterns for this condition, and in population-based rates of hysterectomy. Such variation in the management of a common complaint is an indication for guideline development.

Aim of the Guideline

The aim of this Guideline is to provide recommendations to aid general practitioners and gynaecologists in the initial management of menorrhagia, whether this is initiated in a primary care setting or after referral to a hospital outpatient department. The treatment objective in menorrhagia is to alleviate heavy menstrual flow and, consequently, to improve quality of life. Iron deficiency anaemia must also be prevented.

Guidelines are 'systematically developed statements to assist decisions about appropriate care for specific clinical circumstances'.

Guidelines are not intended to restrict clinical freedom, but practitioners are expected to use the recommendations as a basis for their practice. Local resources and the circumstances and preferences of individual patients will need to be taken into account. Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are highlighted and may form a basis for future research.

Likely costs and benefits

Each year around £7million is spent in the UK on primary care prescriptions to treat menorrhagia. The cost implications of implementing this Guideline have not been considered in detail at this stage. However, no additional costs are anticipated. In producing similar guidelines in New Zealand, it was anticipated that their introduction would lead to savings, mainly by reducing the numbers of hysterectomies. There may be cost savings associated with a reduction in unnecessary tests, or with the avoidance of inappropriate surgical intervention. This may offset the initially higher costs of drug therapy. It is anticipated that there will be health benefits for women complaining of menorrhagia in the form of effective investigation of their presenting problem without delay, more information provision, and appropriate treatment and referral to a specialist if necessary.

Local protocol development, dissemination and implementation

It is anticipated that this national Guideline will be used as the basis for the development of local protocols which will take into account local service provision and the needs and preferences of the local population. Such local adaptation should take place in a similar multidisciplinary group with collaboration between all interested parties that would be affected by the guidelines. It is essential that commissioners of healthcare, as well as

general practitioners and specialists, take part in such a process. A variety of approaches may be necessary to disseminate and implement the local protocols, e.g. distribution of printed protocols to all general practitioners, specialists and trainees, two-hour PGEA sessions for general practitioners, half-day postgraduate meetings in hospitals and audit sessions.

Evidence identification, review and synthesis

A comprehensive literature search was performed to identify relevant evidence on which to base recommendations. MEDLINE, EMBASE, The Cochrane Library and reference lists of review articles were searched up to December 1997. Published systematic reviews or meta-analyses were used if available. Otherwise, relevant randomised controlled trials or other experimental studies were obtained.

Identified articles were assessed methodologically and the evidence was synthesised using qualitative methods. Recommendations were derived using informal consensus methods. Where there were areas without evidence, consensus was again used. The recommendations were then graded according to the level of evidence upon which they were based. The grading used was formulated by the Clinical Outcomes Group (COG) and recommended by the NHS Executive.

Grade A – based on randomised controlled trials

Grade B – based on other robust experimental or observational studies

Grade C – based on more limited evidence but the advice relies on expert opinion and has the endorsement of respected authorities

The strength of the evidence is shown after each recommendation. It is accepted that in this grading system, the evidence itself is not graded although it is described narratively in the text supporting each recommendation. It is also accepted that randomised controlled trials are not the most appropriate study design to investigate diagnostic tests, so using this grading system means that no recommendations concerning diagnostic tests will be graded with an 'A'. Similarly there may be clinical questions that cannot easily be answered by experimental design but nevertheless represent good practice. Such recommendations will automatically be graded 'C'. Other 'C' recommendations may also be questionable as they are not based on incontrovertible evidence. However, the views of the Guideline Group, combined with comments from the extensive peer review, as detailed below, suggest that recommendations with this grading are acceptable to a wide body of expert opinion, pending the results of future research.

Peer review

After the initial draft of the Guideline was written and approved by the Guideline group, a formal peer review process was undertaken. Each member of the Guideline group put forward five to seven names of individuals or organisations from the area of practice that they represented. A copy of the draft Guideline and a Guideline appraisal document, based on that used by the Scottish Intercollegiate Guidelines Network (SIGN), were sent out to 44 nominated people. Thirty replies were received (68% response rate). The comments made by the peer reviewers and the results from the Guideline appraisal document were taken into consideration by the Guideline group before generation of the final Guideline. Under the independent Guideline appraisal system approved by the NHS Executive, the Guideline was sent to a further group of reviewers who particularly concentrated on the methndology used in the development of this Guideline.

Inevitably, a peer review of this extent will mean a regrettable delay between the final literature search and the public appearance of the Guideline.

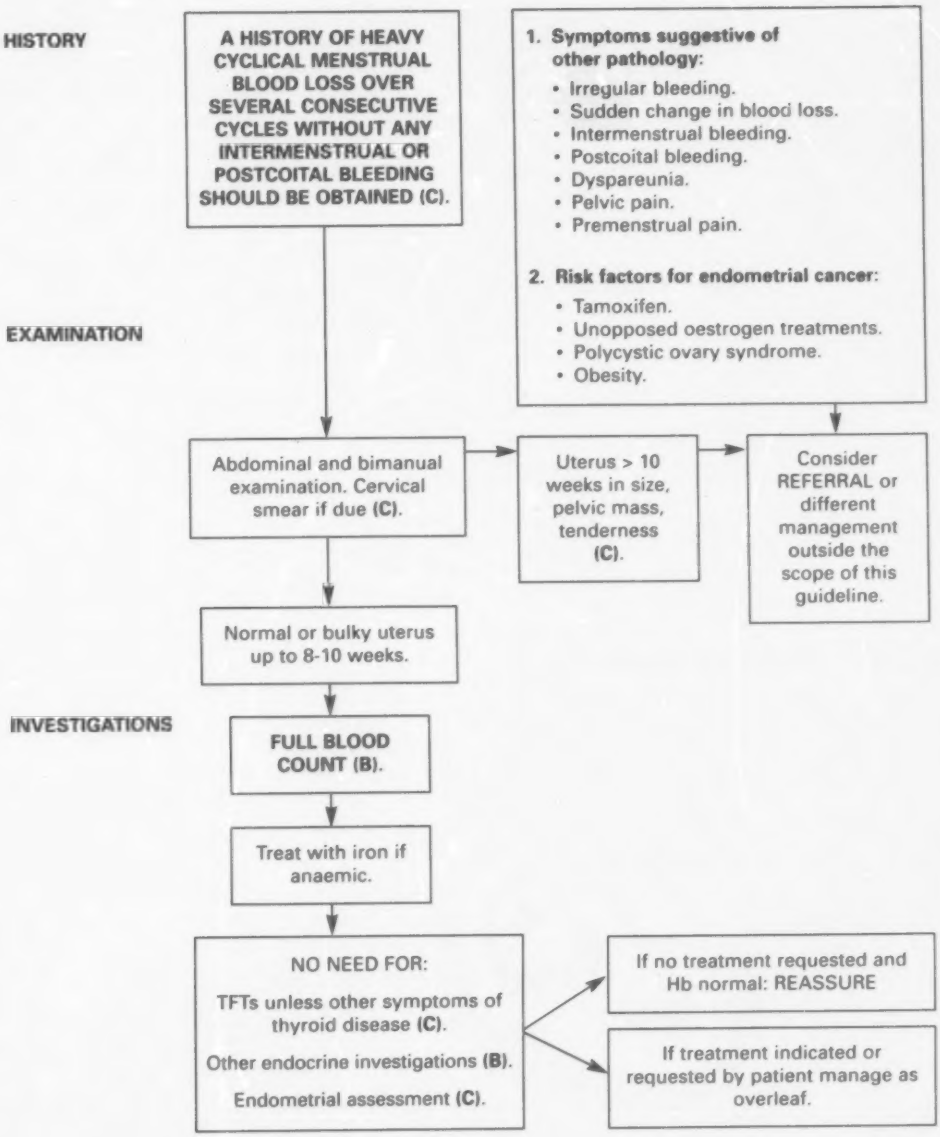
Review of the Guideline

The Guideline will be reviewed no later than three years after its publication, i.e. the year 2002. This will be done by the RCOG, using a similar methodology to that described above. The process will involve updating the literature searches and reviews for each topic to take into account any developments in the area.

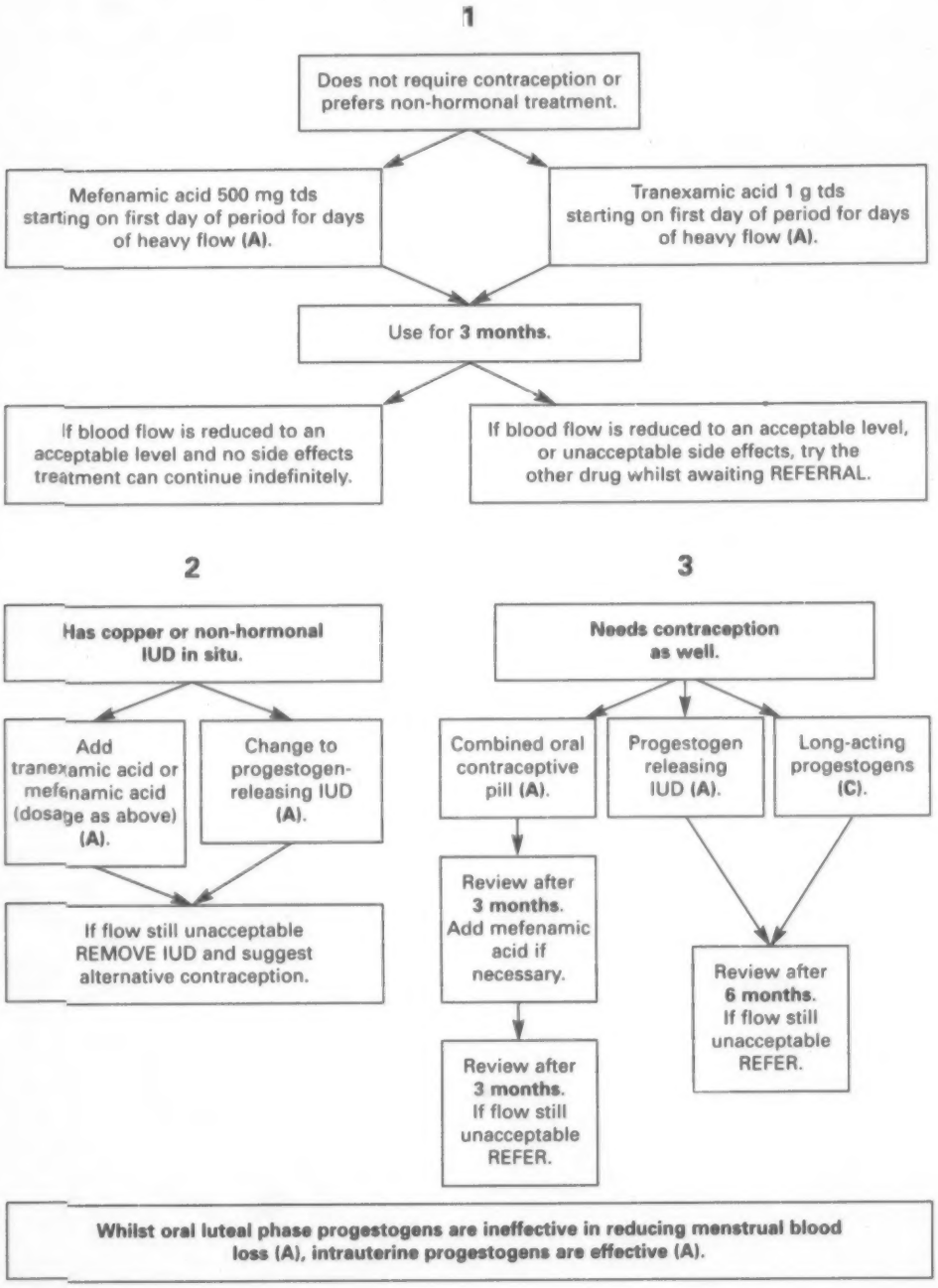
RECOMMENDATIONS

1. A history of heavy cyclical menstrual blood loss over several consecutive cycles without any intermenstrual or postcoital bleeding should be obtained (C).
2. An abdominal and pelvic examination should be performed in all women complaining of menorrhagia (C).
3. full blood count should be obtained in all women complaining of menorrhagia (B)
4. Thyroid function tests do not need to be routinely performed in the initial evaluation of menorrhagia unless the woman has symptoms or signs of hypothyroidism (C).
5. No other endocrine investigations are necessary in the investigation of menorrhagia (B).
6. An endometrial biopsy is not required in the initial assessment of menorrhagia (C).
7. Tranexamic acid and mefenamic acid are effective treatments for reducing heavy menstrual blood loss (A).
8. Antifibrinolytic drugs and non-steroidal anti-inflammatory drugs are both effective in reducing heavy menstrual blood loss in women with intrauterine contraceptive devices (A).
9. Combined oral contraceptives can be used to reduce menstrual blood loss (A).
10. A progestogen-releasing intrauterine device is an effective treatment for menorrhagia (A).
11. Continued use of long-acting progestogens renders most women amenorrhoeic and therefore could be considered for use in menorrhagia (C).
12. Low dose, luteal phase administration of norethisterone is not an effective treatment for menorrhagia (A).
13. Ethamsylate, at currently recommended doses, is not an effective treatment for menorrhagia (A).

CLINICAL EVALUATION OF THE COMPLAINT OF MENORRHAGIA


HISTORY
A HISTORY OF HEAVY CYCLICAL MENSTRUAL BLOOD LOSS OVER SEVERAL CONSECUTIVE CYCLES WITHOUT ANY INTERMENSTRUAL OR POSTCOITAL BLEEDING SHOULD BE OBTAINED (C).
1. Symptoms suggestive of other pathology:
• Irregular bleeding.
• Sudden change in blood loss.
• Intermenstrual bleeding.
• Postcoital bleeding.
• Dyspareunia.
• Pelvic pain.
• Premenstrual pain.
2. Risk factors for endometrial cancer:
• Tamoxifen.
• Unopposed oestrogen treatments.
• Polycystic ovary syndrome.
• Obesity.
EXAMINATION
Abdominal and bimanual examination. Cervical smear if due (C).
Uterus > 10 weeks in size, pelvic mass, tenderness (C).
Consider REFERRAL or different management outside the scope of this guideline.
Normal or bulky uterus up to 8-10 weeks.
INVESTIGATIONS
FULL BLOOD COUNT (B).
Treat with iron if anaemic.
NO NEED FOR:
TFTs unless other symptoms of thyroid disease (C).
Other endocrine investigations (B).
Endometrial assessment (C).
If no treatment requested and Hb normal: REASSURE
If treatment indicated or requested by patient manage as overleaf.

MEDICAL MANAGEMENT OF THE COMPLAINT OF MENORRHAGIA


1
Does not require contraception or prefers non-hormonal treatment.
Mefenamic acid 500 mg tds starting on first day of period for days of heavy flow (A).
Tranexamic acid 1 g tds starting on first day of period for days of heavy flow (A).
Use for 3 months.
If blood flow is reduced to an acceptable level and no side effects treatment can continue indefinitely.
If blood flow is reduced to an acceptable level, or unacceptable side effects, try the other drug whilst awaiting REFERRAL.
2
Has copper or non-hormonal IUD in situ.
Add tranexamic acid or mefenamic acid (dosage as above) (A).
Change to progestogen-releasing IUD (A).
If flow still unacceptable REMOVE IUD and suggest alternative contraception.
3
Needs contraception as well.
Combined oral contraceptive pill (A).
Progestogen releasing IUD (A).
Long-acting progestogens (C).
Review after 3 months. Add mefenamic acid if necessary.
Review after 3 months. If flow still unacceptable REFER.
Review after 6 months. If flow still unacceptable REFER.
Whilst oral luteal phase progestogens are ineffective in reducing menstrual blood loss (A), intrauterine progestogens are effective (A).

Guideline Development Group

The Guideline Development Group was multidisciplinary, with representation from all parties interested in the management of menorrhagia.

Professor R W Shaw,FRCOG (Chairman)
Professor of Obstetrics and Gynaecology, University of Wales, Cardiff
Vice President, RCOG.

Mrs I Allen (Consumer Representative)
Member Consumers' Forum, RCOG.
Head of Social and Health Care Studies, Policy Studies Institute.

Dr M A Harper, FRCOG (Specialist)
Consultant and Senior Lecturer in Obstetrics and Gynaecology, The Queen's University of Belfast.

Dr V Hempsall (Purchaser Representative)
Consultant in Public Health, Dorset Health Authority.

Mrs J Hourahane (Royal College of Nursing Representative)
Gynaecology Service Delivery Unit Manager, John Radcliffe Hospital, Oxford.

Miss M C P Rees MRCOG (Specialist)
Honorary Senior Clinical Lecturer in Obstetrics and Gynaecology and Medical Gynaecologist, University of Oxford.

Professor S K Smith MRCOG (Specialist)
Professor in Obstetrics and Gynaecology, University of Cambridge.

Dr P Sutton (RCGP Representative) General Practitioner; Clinical Research Fellow in the RCGP Audit Unit, Hull.

In addition, two research staff, Dr Kirsten Duckitt and Dr Cristina Augood, worked on the project with administrative assistance from Michael Stillman.

Guidelines Steering Group

Professor Robert Shaw
Vice President of the RCOG (Chairman).

Professor Ian Russell
Professor of Health Sciences, University of York and an expert in Guideline development.

Mr Ralph Settatree
Chairman of the RCOG Audit Committee.

Professor Allan Templeton
Chairman of the RCOG Scientific Advisory Committee.

A representative from the NHS Executive.

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS EVIDENCE-BASED CLINICAL GUIDELINE NO. 5

THE MANAGEMENT OF MENORRHAGIA IN SECONDARY CARE

INTRODUCTION

Menorrhagia has an impact on many women's lives. One in 20 women aged 30-49 consult their general practitioners each year with menorrhagia. Once referred to a gynaecologist, 60% of women with menorrhagia will have a hysterectomy within five years. One in five women in the UK will have a hysterectomy before the age of sixty. In at least half of those who undergo hysterectomies menorrhagia is the main presenting problem. About half of all women who have a hysterectomy for menorrhagia have a normal uterus removed.

There are wide variations in the drugs prescribed in general practice for the management of menorrhagia, in the referral patterns for this condition, and in population-based rates of hysterectomy. Only 58% of women receive medical therapy for their menorrhagia before referral to a specialist. Such variation in the management of a common complaint is an indication for guideline development.

Definition

Menorrhagia is defined, for the purpose of this guideline, as a complaint of heavy cyclical menstrual bleeding over several consecutive cycles.

Menorrhagia can be defined objectively or subjectively. Objective menorrhagia is taken to be a total menstrual blood loss _80ml per menstruation. Subjectively, menorrhagia is defined as a complaint of excessive menstrual blood loss occurring over several consecutive cycles in a woman of reproductive years. The present guideline covers the management of both objective and subjective menorrhagia.

The management of any other abnormalities of the menstrual cycle, e.g. irregular bleeding, is not covered by this guideline.

Aim of the Guideline

The aim of this guideline is to provide recommendations to aid gynaecologists in the management of menorrhagia after referral to the hospital outpatient department and to improve the quality of care provided for women with menorrhagia. The treatment objective in menorrhagia is to alleviate heavy menstrual flow and, consequently, improve quality of life. Iron deficiency anaemia must also be prevented.

Guidelines are "systematically developed statements to assist decisions about appropriate care for specific clinical circumstances". Guidelines are not intended to restrict clinical freedom, but practitioners are expected to use the recommendations as a basis for their practice. Local resources and the circumstances and preferences of individual patients will need to be taken into account. Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are highlighted and may form the basis for future research.

Likely Costs and Benefits

Each year around £7m is spent in the UK on primary care prescribing to treat menorrhagia. The cost implications of implementing this guideline have not been considered in detail at this stage. However, no additional costs are anticipated. In producing similar guidelines in New Zealand, it was anticipated that their introduction would lead to savings, mainly

by reducing the numbers of hysterectomies. When making extrapolations for the UK, variations in service organisation between countries need to be taken into account, as well as the estimates on which the costings were based. There may be cost savings associated with a reduction in unnecessary tests, or with the avoidance of inappropriate surgical intervention. This may offset the initially higher costs of drug therapy. It is anticipated that there will be health benefits for women complaining of menorrhagia in the form of effective investigation and treatment of their presenting problem. Further examination of costs was felt to be outside the scope of this guideline and the guideline group felt that the guideline should be based primarily on the most effective practices, as suggested by the evidence, rather than be directed by cost considerations.

Local Protocol Development

It is anticipated that this national guideline will be used as the basis for the development of local protocols which will take into account local service provision and the needs and preferences of the local population. Such local adaptation should take place in a similar multi-disciplinary group with collaboration between all interested parties that would be affected by the guidelines. It is essential that commissioners of healthcare, as well as general practitioners and specialists, take part in such a process.

Dissemination and Implementation

The recommendations that form the basis of this national guideline will be widely distributed to relevant and interested parties including all Fellows and Members of the RCOG and appropriate purchasers and providers of these health services. The guideline summary is also available on the RCOG website.

A variety of approaches may be necessary to disseminate and implement the local protocols, e.g. distribution of recommendations and algorithms to all specialists and trainees, half-day postgraduate meetings in hospitals, audit sessions and reminders in outpatient clinics. Where possible, patient specific reminders should be developed locally as this method of implementation has been shown to be effective.

Clinical Audit

The recommendations can be translated into standards for use in the local audit of the management of menorrhagia. Suggestions for auditable standards are given. In addition, the algorithm for "The Management of Menorrhagia in Secondary Care" in conjunction with a model outpatient evaluation form that is presented could form the basis for local audit.

Evidence Identification, Review and Synthesis

A comprehensive literature search was performed to identify relevant evidence on which to base recommendations. MEDLINE, EMBASE, The Cochrane Library and reference lists of review articles were searched up to February 1998. Published systematic reviews or meta-analyses were used if available. Otherwise relevant randomised controlled trials or other experimental studies were obtained. Identified articles were assessed methodologically and the evidence was synthesised using qualitative methods. Recommendations were derived using informal consensus methods. Where there were areas without evidence, consensus was again used. The recommendations were then graded according to the level of evidence upon which they were based. The grading used was formulated by the Clinical Outcomes Group (COG) and recommended by the NHS Executive.

A – based on randomised controlled trials

3 – based on other robust experimental or observational studies

C – based on more limited evidence but the advice relies on expert opinion and has the endorsement of respected authorities

The strength of the evidence is reflected in the grading of each recommendation. It is accepted that randomised controlled trials are not the most appropriate study design to investigate diagnostic tests so using this grading system means that no recommendations concerning diagnostic tests will be graded with an A recommendation. Similarly there may be clinical questions that cannot easily be answered by experimental design but nevertheless represent good practice. Such recommendations will automatically be graded "C". Other "C" recommendations may also be questionable as they are not based on incontrovertible evidence. However, the views of the guideline group combined with comments from the extensive peer review, as detailed below, suggest the recommendations with this grading are acceptable to a wide body of expert opinion pending the results of future research. The grading does not reflect the clinical importance of the recommendations, only the relationship of the recommendation to the available evidence.

Peer Review

After the initial draft of the guideline was written and approved by the guideline group, a formal peer review process was undertaken. Each member of the guideline group put forward 5-7 names of individuals or organisations from the area of practice that they represented, so a multi-disciplinary mix of reviewers was ensured. A copy of the draft guideline and a guideline appraisal document, based on that used by the Scottish Intercollegiate Guidelines Network (SIGN), were sent out to 38 nominated peer reviewers. Twenty seven people replied giving a response rate of 71%. The comments made by the peer reviewers and the results from the guideline appraisal document were taken into consideration before generation of the final guideline. All comments from the peer review were discussed by the guideline group and amendments agreed by informal consensus. There was little dissension among the peer reviewers with regard to the main substance of the guideline. Suggested amendments concerned style, presentation and clarity. None of the recommendations was substantially changed as a result of the peer review.

Review Of The Guideline

The guideline will be reviewed no later than three years after its completion i.e. the year 2003. This will be done by the RCOG, using a similar methodology as described above. The process will involve updating the literature searches and reviews for each topic to take into account any new developments in the area.

RECOMMENDATIONS

Indications

1. If a woman continues to complain of heavy menstrual bleeding, despite having used a drug treatment recommended in the first guideline, her menstrual history should be re-evaluated and an abdominal, bimanual and speculum examination performed (C).

Investigations

2. A full blood count should be performed (B).
3. Tests for thyroid function and bleeding disorders should only be performed if there are suggestive features present in the history or on examination (C).
4. No other endocrine investigations are necessary in the investigation of menorrhagia (B).
5. The uterine cavity should initially be investigated using transvaginal ultrasound (B).
6. An endometrial biopsy should be considered for all women with persistent menorrhagia (C).
7. A D&C does not give additional diagnostic information over and above a hysteroscopy with endometrial biopsy (B).
8. When hysteroscopy is indicated, it allows direct visualisation of the uterine cavity and the opportunity for an endometrial biopsy without the need for a general anaesthetic (A).

9. Consideration should be given to performing an objective or semi-objective measurement of menstrual blood loss before deciding upon definitive surgical treatment (C).

Treatment

Patient Issues

10. Patients must be involved in the decision making process regarding their treatment and be provided with appropriate information to enable them to do this (C).
11. If definitive surgical treatment is intended, the likely outcomes and complications should be discussed with the woman beforehand. These discussions should be backed up with appropriate written information (C).
12. Quality of life issues are important and must be addressed during the collaborative decision making process (C).

Drug Treatments

13. Second line drugs such as danazol, gestrinone, and gonadotrophin releasing hormone analogues are effective in reducing heavy menstrual blood loss but side effects limit their long-term use (A).
14. A progestogen releasing IUD is an effective treatment for reducing heavy menstrual blood loss and should be considered as an alternative to surgical treatment (A).

Surgical Treatments

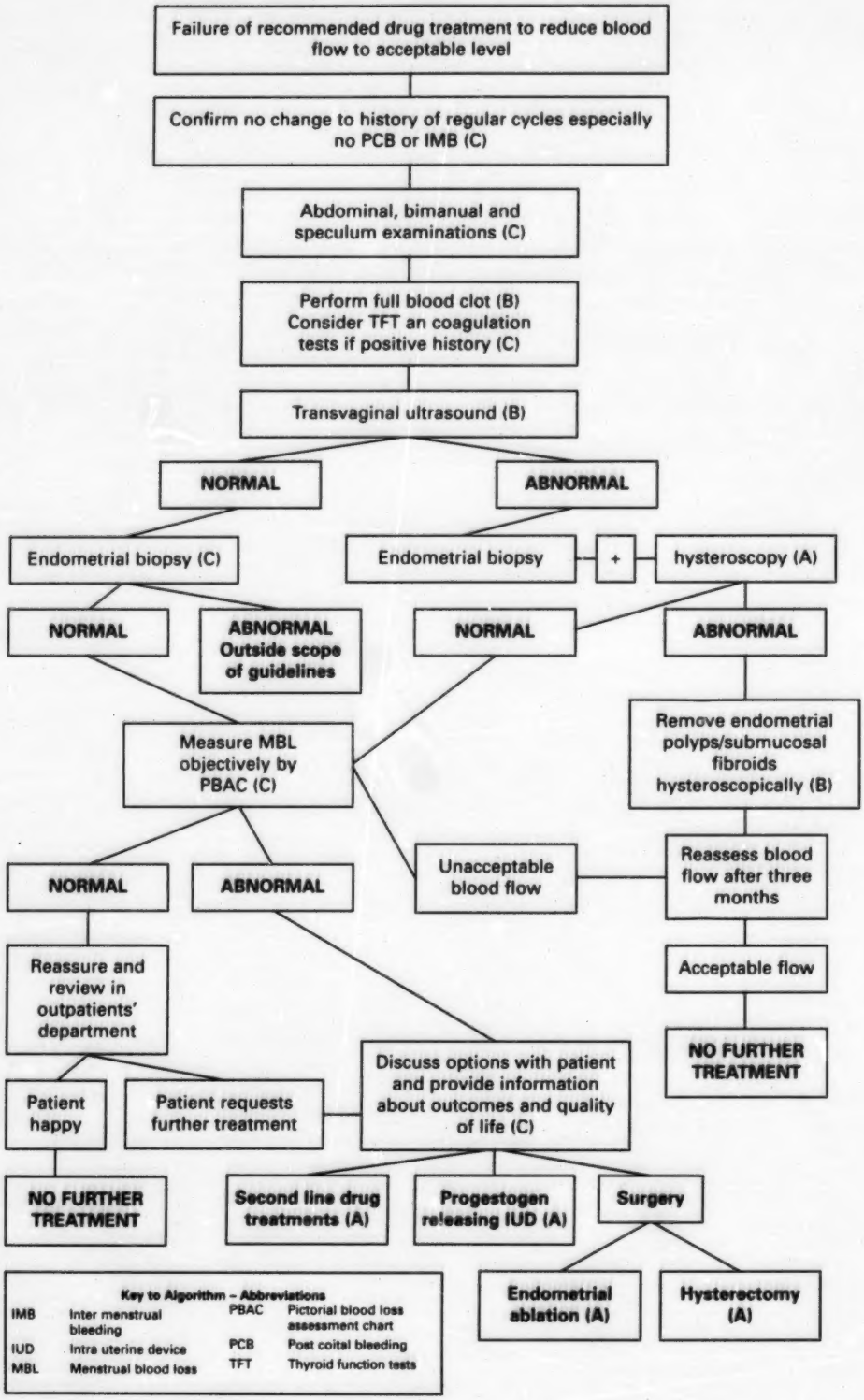
15. A D&C is not therapeutic in cases of heavy menstrual bleeding (B).
16. If intrauterine pathology such as sub-mucous fibroids or polyps are found during ultrasonic or hysteroscopic investigation, these should be removed hysteroscopically (B).
17. Endometrial ablative procedures are effective in treating menorrhagia (A).
18. Hysterectomy is an established, effective treatment for menorrhagia (A).
19. The widespread use of hysterectomy as a treatment for menorrhagia should be balanced against its potential mortality and morbidity (C).
20. Prophylactic antibiotics should be given to all women undergoing major surgical treatment for menorrhagia (A).
21. Risk factors for venous thromboembolism should be assessed before hysterectomy and appropriate prophylactic measures instituted (C).

Key to grading of recommendations

A – based on randomised controlled trials

B – based on other robust experimental or observational studies

C – based on more limited evidence but the advice relies on expert opinion and has the endorsement of respected authorities


Failure of recommended drug treatment to reduce blood flow to acceptable level
Confirm no change to history of regular cycles especially no PCB or IMB (C)
Abdominal, bimanual and speculum examinations (C)
Perform full blood clot (B) Consider TFT an coagulation tests if positive history (C)
Transvaginal ultrasound (B)
NORMAL
ABNORMAL
Endometrial biopsy (C)
Endometrial biopsy
+
hysteroscopy (A)
NORMAL
ABNORMAL Outside scope of guidelines
NORMAL
ABNORMAL
Measure MBL objectively by PBAC (C)
Remove endometrial polyps/submucosal fibroids hysteroscopically (B)
Unacceptable blood flow
Reassess blood flow after three months
NORMAL
ABNORMAL
Acceptable flow
Reassure and review in outpatients' department
NO FURTHER TREATMENT
Discuss options with patient and provide information about outcomes and quality of life (C)
Patient happy
Patient requests further treatment
NO FURTHER TREATMENT
Second line drug treatments (A)
Progestogen releasing IUD (A)
Surgery
Endometrial ablation (A)
Hysterectomy (A)
Key to Algorithm – Abbreviations
IMB Inter menstrual bleeding
IUD Intra uterine device
MBL Menstrual blood loss
PBAC Pictorial blood loss assessment chart
PCB Post coital bleeding
TFT Thyroid function tests

GUIDELINE DEVELOPMENT GROUP

The guideline group was multi-disciplinary with representation from all parties interested in the management of menorrhagia.

Professor R W Shaw, FRCOG (Chairman) - Professor of Obstetrics and Gynaecology, University of Wales, Cardiff; President RCOG.

Mrs I Allen (Consumer representative) - Member Consumers' Forum RCOG, Head of Social and Health Care Studies at the Policy Studies Institute;

Dr M A Harper, FRCOG (Specialist) - Consultant and Senior Lecturer in Obstetrics and Gynaecology, The Queen's University of Belfast.

Dr V Hempsall (Purchaser representative) - Consultant in Public Health, Dorset Health Authority.

Mrs J Hourahane (Royal College of Nursing representative) - Gynaecology Service Delivery Unit Manager, John Radcliffe Hospital, Oxford.

Miss M C P Rees MRCOG (Specialist) - Honorary Senior Clinical Lecturer in Obstetrics and Gynaecology and Medical Gynaecologist, University of Oxford.

Professor S K Smith MRCOG (Specialist) - Professor in Obstetrics and Gynaecology, University of Cambridge.

Dr P Sutton MRCGP (RCGP representative) - General Practitioner, Brigg, South Humberside.

In addition, two research staff, Dr Kirsten Duckitt and Dr Cristina Augood, worked on the project with administrative assistance from Michael Stillman.

GUIDELINES STEERING GROUP

Professor Robert Shaw, Professor of Obstetrics and Gynaecology, University of Wales, Cardiff and President of the RCOG (Chairman).

Mr Steve Pugh, NHS Executive representative.

Professor Ian Russell, Professor of Health Sciences, University of York and an expert in guideline development.

Mr Ralph Settatree, Consultant Obstetrician and Gynaecologist and Past-Chairman of the RCOG Audit Committee.

Professor Allan Templeton, Professor of Obstetrics and Gynaecology, University of Aberdeen, Honorary Secretary of the RCOG and Past-Chairman of the RCOG Scientific Advisory Committee.

APPENDIX I – REFERENCES

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